UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1 / TVT EXACT CASES**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF JERRY G. BLAIVAS, M.D.

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. My opinions are as follows:

I. QUALIFICATIONS

Dr. Blaivas is a board certified urologist in the state of New York. He attended Tufts College for his bachelor's degree in 1964 and Tufts University School of Medicine for his medical doctorate in 1968. He completed a urology residency in 1976 after completing a general surgery internship followed by a two year general surgery residency. He has been teaching medicine since 1976 at Tufts University School of Medicine, Columbia University, Cornell University and most recently, SUNY Downstate Medical School. Throughout his academic career, Dr. Blaivas remained a practicing surgeon in a number of hospitals in Massachusetts and New York, and is currently an attending surgeon at The New York Presbyterian Hospital and Lenox Hill Hospital.

Dr. Blaivas is one of the pioneers of sling surgery for women with sphincteric incontinence. He performed his first autologous rectus fascial sling operation in 1981 and shortly thereafter modified the technique by creating a fascial graft instead of a fascial flap which was the prevailing method at the time. The reason for this change is that the flap was tethered by its abdominal attachments such that it was very difficult to place the sling loosely enough to avoid causing urethral obstruction. Once that modification was adapted, it was much easier to place the sling without any tension at all and that principle became the guiding principle for the subsequent development of synthetic mesh slings. In 1998, Dr. Blaivas, in a peer review journal, proposed that rectus fascial sling be considered a suitable operation for all women with sphincteric incontinence. Prior to that time, it was considered to be indicated only in women with complicated problems who had failed prior incontinence operations.

In the 1980's, Dr. Blaivas became acquainted with severe complications that resulted from synthetic mesh slings composed of Marlex and Mersilene. He performed a number of surgeries to remove these slings because of severe, refractory complications including pain, infection, erosion and urinary fistula. So difficult and problematic were these complications that Dr. Blaivas traveled to Toronto and spent some time with Ted Morgan, MD – a gynecologist who performed the largest number of these operations in the peer review literature. Dr. Morgan was considered to be a highly qualified surgeon, but even in his hands devastating complications occurred and they often occurred years after the original surgery. In the hands of less skilled surgeons, the complication rate was much higher. Dr. Blaivas discussed the surgical technique of sling surgery and methods of treating complications in great detail with Dr. Morgan. He concluded that: 1) even in the hands of a master surgeon, devastating complications could occur with synthetic slings, but rarely if ever occurred with autologous fascial (graft) slings; 2) in the hands of inexperienced surgeons, the complication rate could be unacceptably high; 3) removal of the mesh was exceedingly difficult and fraught with its own complications; 4) once a complication occurred, the chances of a successful outcome are low; and 5) the mesh itself, because it is a foreign body, contributes significantly to the complication rate. Because of these known complications and the technical difficulties performing mesh surgery, the operation fell out of favor until synthetic slings were revived, reinvented and promoted by industry through pervasive advertising and inducements to physicians to perform such surgeries.

Dr. Blaivas himself was heavily "recruited" by manufacturers of synthetic slings to become a "key opinion leader" and promote sling surgery. He was thoroughly vetted by industry representatives and Peter Petros, MD, one of the pioneers of synthetic sling surgery, spent a week with him in New York at his office and in the operating room discussing and demonstrating the theory and surgical technique of synthetic sling surgery. It was during this period of time that Dr. Blaivas decided to perform some synthetic slings in highly selected patients because the procedure could be performed so quickly and with so small an incision. Once he became adept at the technique through simulated training, he realized that there really wasn't any need for the "sling kit" that was supplied by the manufacturer. Further, he thought that the technique of passing the trocars from the vagina upwards to the abdomen was a much more dangerous technique that could lead to adjacent organ injury. So, instead, he fashioned a strip of "Gynemesh" and used a Stamey needle to pass the trocars from the abdomen to the vagina. He further modified the technique to include dissection alongside the urethra into the retropubic space, nearly eliminating the possibility of injuring the bladder or urethra or adjacent organs with the trocars.

In essence, Dr. Blaivas was using exactly the same technique he used for rectus fascial slings (which was considered the gold standard for incontinence surgery) and simply replaced the rectus fascial graft with a synthetic graft. Dr. Blaivas considered that synthetic slings, using the technique described here, could actually improve sling surgery provided that the new meshes were improved to the point that they had an acceptable safety profile and, in fact, he opined that synthetic slings will become the standard once the bugs were worked out. But to date, that has not happened. Throughout this time (the last decade of the 20th and first decade of the 21st century), Dr. Blaivas became increasingly aware of devastating, life threatening, and life style altering complications of synthetic sling surgery and became a world renowned expert at treating those complications. He has personally operated on about 75 – 100 patients with severe synthetic mesh

complications, and taken care of hundreds more who either did not elect further surgery or who simply gave up and were seeking relief from pain management experts. He has also discussed these issues with his peers. It is that experience, supported by peer-reviewed scientific literature, which forms the basis of the following opinions.

In August, 2015, Dr. Blaivas published the review article, "Safety considerations for synthetic sling surgery" in Nature Reviews Urology. The Nature family of journals is regarded as one, if not *the* premier resource for scientific research in the world.[1] Publication in Nature Reviews Urology, requires that the article meet strict criteria.[2] In its final version, the article was a herculean project - naming nine authors, spanning 29 pages, and containing 397 references. The exhaustive research presented in this paper further supports the opinions.

All of these opinions are to a reasonable degree of medical certainty. He applied the same scientific rigor that he use in all aspects of his professional activities, including caring for patients, publishing, lecturing, consulting with other health care professionals, and serving as a litigation expert. The methodology he used in rendering my opinions is the same that he uses in his professional activities. His opinions have been consistent over time and do not differ just because they are provided for various purposes or audiences.

Dr. Blaivas' Curriculum Vitae is attached hereto and by reference made a part hereof. Please see Exhibit "A" attached.

II. DISCUSSION OF OPINIONS

1. The Gynecare TVT-Exact is a polypropylene mesh product made and marketed by Ethicon to allegedly treat stress urinary incontinence ("SUI"). The TVT Exact consists of:

- PROLENE® polypropylene Laser Cut Mesh with a polyethylene sheath or covering and attached trocars / surgical devices
- Instructions for use (IFU)
- A TVT Reusable Rigid Catheter Guide is available separately

2. From the time it was introduced to the market through January 2015, the IFU for the TVT Exact did not change. In January 2015, Ethicon introduced a new IFU[3] with some modifications, as discussed below.

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[1] "The Nature Reviews clinical journals commission leaders in the field to write clinical content of the highest quality, authority and accessibility. Content is subject to rigorous review by our in-house editors and/or peer-review, and counsel is provided by the Editors-in-Chief and an international Advisory Boards to ensure comprehensive coverage of topical issues." Nature.com accessed 12/18/2015.

[2] The criteria for publication include: Timely, accurate and balanced; Important for practicing doctors, researchers and academics in the subspecialty; Interesting and accessible to practicing doctors, researchers and academics in wider specialties. Nature.com accessed 12/18/2015.

[3] 1/2015 TVT Exact IFU from Ethicon website

3. The TVT-Exact was launched by Ethicon in 2010. It was designed as a modified TVT-R and included the following changes: (1) a smaller diameter trocar for placement; (2) changes in the packaging and sheath; and (3) made only from LCM, not mechanically cut mesh.[4]

4. The new smaller diameter trocar tips created issues unique to the TVT Exact. Ethicon received complaints of the trocar tips bending and breaking off during operative procedures.[5] Instead of addressing the defect in the product, Ethicon dismissed the concerns of it salesforce[6] by blaming the problems on the implanting physicians.[7]

5. Ethicon did not address these issues until 2013 when it began a design change for the TVT Exact, including a review of the IFU and modification of the trocar shaft and sheath inner tip.[8] Eventually, the tip of the trocar was changed from a "Chamfer tip" to a tapered tip; however, Ethicon did not alert implanting physicians to the problems in the original tip or the change to the tapered tip.[9]

6. Ethicon admitted that it did not have any clinical data on the TVT Exact and that it relied on the data from the TVT.[10]

7. Ethicon divided products into "promoted" and "non-promoted" groups. The TVT was placed into the non-promoted category after the TVT Exact was launched because Ethicon could charge a 10% price premium for the TVT Exact.[11]

8. The Gynecare TVT Exact should not have been designed for placement in a surgically contaminated field[12] without proper animal and clinical studies to document safety and without a clear warning about the possibility of short and long term complications.[13] Bacteria attaches to mesh during the insertion process and can cause both acute and chronic infections in women.[14] Infection, even subclinical, can result in chronic inflammation, scarring, pain, abscess, vaginal, bladder and urethral erosion and other complications.

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[4] ETH.MESH.01251155; ETH.MESH.00177539; ETH.MESH.02104810
[5] ETH.MESH.03573067; ETH.MESH.12881753 at 1758-69; ETH.MESH.18645133
[6] ETH.MESH.08578490 at 8492;
[7] ETH.MESH.08578490 at 8491; ETH.MESH.08582600.
[8] ETH.MESH.15236825; ETH.MESH.12868401; ETH.MESH.12869193
[9] ETH.MESH.12844215
[10] ETH.MESH.09199174
[11] ETH.MESH.00541700; ETH.MESH.01678349
[12] E.g., Culligan P, Heit, M., Blackwell, L., Murphy, M., Graham, C. A., & Snyder, J. Bacterial colony counts during vaginal surgery. Infectious Dieseases in Obstetrics and Gynecology. 2003;11(3):161-5.
[13] E.g., Vollebregt A, Troelstra, A., & van der Vaart, C. H. . Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful? International Urogynecology Journal and Pelvic Floor Dysfunction.2009: 20(11):1345-51; Choi JJ, Palaniappa, N. C., Dallas, K. B., Rudich, T. B., Colon, M. J., & Divino, C. M. Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases. Annals of Surgery. 2012;255(1):176-80.
[14] E.g., Vollebregt, 2009; Choi, 2012; Klinge U, Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. Shrinking of polypropylene mesh in vivo: an experimental study in dogs. The European Journal of Surgery. 1998;164(12):965-9.

9. The Gynecare TVT Exact causes serious and life-style altering complications including but not limited to chronic pelvic pain syndromes, chronic dyspareunia and sexual impairment, nerve injuries, de novo urinary symptoms, infections, fistulas, urethral obstruction, urethral strictures, bladder stones, death, vaginal, urethral, and bladder erosions, pelvic organ dysfunction, pelvic anatomy distortion, and other complications. These complications often require reoperation and are sometimes permanent. Because of these complications, the risks of these devices outweigh the benefits. I also am aware of many complications including deaths, injury to the iliac artery and vein, bowel injury and ureteral injuries despite the fact that virtually none of these complications were reported in the peer review literature.[15] Many of these complications can occur many years or even decades after the original surgery.[16]

10. The management of many sling complications is fraught with complexity and results in a high rate of persistent symptoms.[17] This has been evident since the complications from the Mersilene, Marlex, Gore-Tex, and Protogen slings that were performed during the last three decades of the 20th century and more recently the Protegen and Mentor ObTape slings. Further Ethicon knew or should have known about the contemporaneous complications that were occurring with their devices[18] and with the devices of their competitors. From a scientific and ethical perspective, Ethicon should have had a high index of suspicion relating to the product defects based on the previous experiences with other synthetic products. For retropubic synthetic slings, the most devastating complications are those that are due to vascular and bowel injuries and a number of deaths have been reported from these.[19]

11. The two most debilitating and challenging complication to treat are chronic pain and urinary fistulas. This pain can be located in the abdomen, pelvis, vagina, buttocks, perineum, groin, thigh, or leg. It can be acute (occurring immediately after surgery) or chronic with an insidious onset. It is often refractory to traditional treatments. It can be related to erosion; scarring; mesh deformation; entrapment or compression of large nerves with classic or atypical nerve distribution; entrapment of smaller nerve branches with diffuse distribution; muscular inflammation, scarring, trauma, and hypertonicity; visceral pain syndromes; and other complications. It can be associated with other sensory changes such as numbness and tingling.

12. Chronic Mesh Pain Syndrome (CMPS) has been described in the medical literature. The syndrome is characterized by the transformation of vaginal pain into a multi-organ system process.

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[15] E.g.,Petri, 2012; Rogo-Gupta, 2013; Ross S, Robert M, Swaby C, Dederer L, Lier D, Tang S, et al. Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. Obstetrics and gynecology. 2009;114(6):1287-94; Cholhan HJ, Hutchings TB, Rooney KE. Dyspareunia associated with paraurethral banding in the transobturator sling. American journal of obstetrics and gynecology.

[16] Boyles SH, Edwards R, Gregory W, Clark A. Complications associated with transobturator sling procedures. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(1):19-22; Parnell BA, Johnson EA, Zolnoun DA. Genitofemoral and perineal neuralgia after transobturator midurethral sling. Obstetrics and gynecology. 2012;119(2 Pt 2):428-31.

[17] E.g., Deng DY, Rutman, M., Raz, S., & Rodriguez, L.V. Presentation and management of major complications of midurethral slings: Are complications underreported? Neurourology and Urodynamics. 2007;26(1):46-52.

[18] ETH.MESH.18645133; ETH.MESH.02620354; ETH.MESH.02621559; ETH.MESH.02622456; ETH.MESH.02622954; ETH.MESH.02625055; ETH.MESH.02626378; ETH.MESH.18882038; ETH.MESH.02628698; ETH.MESH.02630134

[19] E.g., ETH.MESH.00660488.

The pain is considerably greater and lasts longer than routine post-operative pain and treatment is extremely challenging.[20] The pain may continue, or even worsen, after mesh excision or revision. Completely new treatment modalities for pelvic pain have been developed as a response to this pain management challenge, including trigger point injections, nerve blocks, Botox injection, pelvic floor physical therapy, treatment with medications for chronic, neuropathic pain, and referral to contract-based pain management programs. These were extremely rarely used in urology or gynecology until the appearance of mesh-related pain.[21]

13. These and other complications may occur even in experienced hands and when proper surgical technique is used. Ethicon's marketing materials suggest that these complications occur mostly because of faulty surgical technique performed by inexperienced or poorly trained surgeons, perhaps by "over-tensioning" or misplacement. However, I have firsthand knowledge that is not the case. For example, I operated on one woman who had urethral erosion of synthetic mesh three years after it was implanted by one of our former fellows, whose expertise I am 100% confident of. Further, because of an unrelated episode of hematuria two years after implantation, she underwent cystoscopy which showed no signs of mesh erosion, yet one year later she was found to have erosion that also caused a urethral stricture. In the course of my practice, I have seen mesh complications from many world renowned experts, including physicians that Ethicon has retained as experts in litigation, and, from discussions with my colleagues, I know of many others. In the majority of cases that I see in my practice and that are reported in the literature, the device was placed in accordance with the manufacturers recommendations for placement.

14. Even the simplest complications are often more complicated than they appear. It is commonly stated that when there is extrusion of the mesh through the vaginal wall, it is quite a simple thing to just trim the edges of the exposed sling and either create small vaginal wall flaps to cover the defect or simply leave the wound open and apply estrogen. However, the studies that report successful outcomes generally have a short follow-up and the outcomes may be much worse than they appear.[22] In my own personal experience, I have seen many patients who were treated this way who came back months, years, and even decades later with more extrusions and granulomas that proved almost impossible to "cure."[23] These persistent and recurrent erosions are also reported in the medical literature and in Ethicon's own documents.[24]

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[20] E.g., Rogo-Gupta, 2013.

[21] E.g.,Petri, 2012; Rogo-Gupta, 2013; Ross S, Robert M, Swaby C, Dederer L, Lier D, Tang S, et al. Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. Obstetrics and gynecology. 2009;114(6):1287-94; Cholhan HJ, Hutchings TB, Rooney KE. Dyspareunia associated with paraurethral banding in the transobturator sling. American journal of obstetrics and gynecology;202(5):481 e1-5; Boyles SH, Edwards R, Gregory W, Clark A. Complications associated with transobturator sling procedures. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(1):19-22; Parnell BA, Johnson EA, Zolnoun DA. Genitofemoral and perineal neuralgia after transobturator midurethral sling. Obstetrics and gynecology. 2012;119(2 Pt 2):428-31

[22] E.g., Blaivas, 2015

[23] E.g., Reynolds WS, Kit, L., Kaufman, M.R., Karram, M., Bales, G.T., and Dmochowski, R. Obturator Foramen Dissection for Excision of Symptomatic Transobturator Mesh. The Journal of Urology. 2012;187(5):1680-4.; Blaivas, 2013

[24] E.g., Petri, 2012; Abbott, 2014; Hansen, 2014; Unger, 2014; Rogo-Gupta, 2013; Shah , 2013; Dunn, 2014; Hammett, 2014; ETH.MESH.01706065 at 3.

15. Given the increasing number of mesh sling operations performed and the complexity of surgery to repair the complications, there are an increasing number of patients who have failed initial treatments and an increasing number of "mesh cripples". As more slings implantations are being performed and the longevity expectations of patients are increasing, it has become apparent that unanticipated, serious, and sometimes lifestyle- altering complications can occur that are not only unique to patients with slings but are also often refractory to treatment.[25] Other authors of recent peer-reviewed articles agree. Lee states that the use of synthetic material has generated novel complications, including mesh extrusion, pelvic and vaginal pain and mesh contraction, requiring a new classification system for complications relating to prosthesis insertion. He coined the term "Meshology" – an evolving field of sub-specialization dedicated to a growing population of affected women with complications from synthetic materials.[26] Barski also described mesh-related complications as "a current emerging problem, which confronts all urologists and gynecologists in their daily practice."[27]

16. The retropubic approach, such as that described in the Gynecare TVT Exact IFU and taught by Ethicon, increases the risk and incidence of bladder perforations, bowel perforations, and other disastrous intraoperative events.[28]

17. Claims that make the procedure sound as if it is safer and easier to perform than it actually is are misleading. See above. Ethicon's initial concept for this product was sound – a simple, safe, efficacious, outpatient procedure that required minimal surgical skills and could be mastered by surgeons with little training. But the reality of the Gynecare TVT Exact is very different from this concept. It is not easy to learn these techniques and the ergonomics of the trocars is such that, even for the most skilled surgeon, it is easy to misguide them and end up in the wrong anatomical location. There is ample evidence in the literature that it is very common for the trocars to inadvertently puncture the bladder or urethra during trocar passage.[29]

18. There is little margin of error when placing a retropubic sling, such as the Gynecare TVT Exact. The procedure involves the blind passage of trocars though the vagina and passing through or in close proximity to the following structures: bladder, bowels, anterior vaginal wall, arcus tendineus fascia pelvis, urethra, the obturator neurovascular bundle, and venous plexus of Santorini and then out two small incisions above the pubic bone. If it is located too superficially (i.e., between the vaginal epithelium and the pubocervical fascia), vaginal extrusion might occur. Conversely, a Gynecare TVT Exact that is too deep (i.e., to the pubocervical fascia) can cause urethral or bladder erosion. In my experience training fellows and residents, I was struck by what a difficult time they had finding the correct plane, how much bleeding they got into during the

[25] Blaivas 2015, 481.
[26] Lee 2015, 202.
[27] Barski and Deng 2015, p6.
[28] E.g., Brubaker, L., et al. (2011). "Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study." Am J Obstet Gynecol 205(5): 498 e491-496; Deng, 2007; Olagundoye, V. O., et al. (2007). "Delayed presentation of small bowel trauma during insertion of tension free vaginal tape (TVT) sling." J Obstet Gynaecol 27(1): 92-93.
[29] E.g., Bhoyrul S, Vierra MA, Nezhat CR, Krummel TM, Way LW. Trocar injuries in laparoscopic surgery. Journal of the American College of Surgeons. 2001;192(6):677-83; Shindel AW, Klutke CG. Urethral slings placed by the transobturator approach: evolution in the technique and review of the literature. Curr Urol Rep. 2005;6(5):385-92.

dissection and how often they injured or almost injured the bladder or urethra during the dissection and/or passing the trocar. In fact, the bladder or urethra perforation occurred at a mean incidence of about 3% (range 0-16%).[30] Perforation of the bladder, bowel, urethra, or vagina during the original implantation surgery dramatically increases the risk of subsequent sling erosion 26 fold.[31]

19. Furthermore, the location of anatomical structures varies from individual to individual and even in the same individual, making accurate placement unpredictable. For example, positioning of the patient in various degrees of dorsal lithotomy position can impact the locations of nerves and blood vessels relative to surface landmarks. Further, the size of the obturator foramen and the bony pelvis can vary.[32] Since the Gynecare TVT Exact normally passes dangerously close to vital structures, the anatomic and positional variations render trocar passage more hazardous than theoretic considerations would suggest.[33] Further, although bleeding can usually be controlled or is self-limited, nerve injuries can have disastrous long term consequences.

20. Removal of the Gynecare TVT Exact is technically difficult and requires considerable surgical expertise that many implanting surgeons do not possess. Due to tissue ingrowth, it is very difficult and sometimes impossible to remove the entire mesh and, in most instances, there are remnants of mesh that remain. This is well documented in the medical and scientific literature.[34] Further, there is a high likelihood of injuring adjacent structures and failing to alleviate symptoms, especially those related to pain, during removal surgery. There is a high incidence of recurrent sphincteric incontinence, requiring yet another procedure to repair it – ideally an autologous sling. Remnants of the partially removed Gynecare TVT Exact can also migrate.[35] All of these procedures create more scar tissue in the pelvis, which further compromises the functionality of the pelvic anatomy and causes additional complications for women.

21. When the sling has been incorporated into the wall of the urethra or bladder, it is necessary to excise a portion of those structures in order to completely remove the mesh and, in so doing, there is a high likelihood of causing an urethrovaginal or vesicovaginal fistula. I have seen a number of such complications.[36] In order to prevent these fistulas, it is necessary to reconstruct the lower urinary tract and this usually requires considerable surgical expertise and experience utilizing plastic surgery techniques.[37]

22. When fistulas complicate mesh sling surgery, the outlook is grave. Although the reported incidence of mesh related fistulas is low (less than 1%), the success rate of surgical repair is low,

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[30] E.g., Blaivas, 2015.

[31] E.g., *Id.*, Osborn, D. J. et al. Analysis of patient and technical factors associated with midurethral sling mesh exposure and perforation. Int. J. Urol. 11, 1167–1170 (2014).

[32] E.g., Whiteside JL, Walters MD. Anatomy of the obturator region: relations to a trans-obturator sling. Int Urogynecol J Pelvic Floor Dysfunct. 2004;15(4):223-6; Litwiller JP, Wells RE, Jr., Halliwill JR, Carmichael SW, Warner MA. Effect of lithotomy positions on strain of the obturator and lateral femoral cutaneous nerves. Clinical anatomy. 2004;17(1):45-9.

[33] E.g., Bhoyrul, 2001; Shindel, 2005.

[34] E.g., Blaivas, 2015; Blaivas, 2013; Shah, 2013.

[35] E.g., Blaivas, 2015

[36] E.g., Blaivas. 2014.

[37] E.g., Blaivas, 2008.

40% in our published experience. I have personally repaired approximately 200 vesicovaginal fistulas and approximately 150 urethrovaginal fistulas. With respect to fistula repair, I am only aware or seven failures in my series, four of whom were associated with mesh slings.[38]

23. The Gynecare TVT Exact is not safer or less invasive overall than the alternative procedures. Furthermore, I have seen no evidence that Ethicon studied or evaluated the safety and efficacy of the insertion technique it developed and sold as part of the Gynecare TVT Exact device or researched potential alternatives to minimize complications. Even though the IFU says the procedure can be done under local anesthesia it also says it can be done using regional or general anesthesia. Ethicon knew that surgeons generally were more comfortable using general anesthesia and did not inform them that Ulmsten, the inventor of the Gynecare TVT device, had performed the procedure using local anesthesia and that using general anesthesia increased the risk of urinary retention and erosion and decreased the chance of successful outcomes for patients.[39]

24. Pubovaginal slings using autologous fascia are as effective as the Gynecare TVT Exact. In my own personal series and according to several peer review meta-analyses and the AUA guideline panel the success rate for autologous slings is comparable to synthetic mesh slings.[40]

25. Pubovaginal slings using autologous fascia are safer than synthetic slings with respect to serious complications such as lifestyle altering pain, dyspareunia, vascular, erosion, bowel and lower urinary tract injury, and other complications. Although the reported incidence of urinary retention is slightly higher, much of the data to support that comes from an era before the importance of a tension free repair was known. Using current technique, urinary retention is comparable amongst autologous and synthetic slings.[41]

26. These types of serious complications do not occur or occur very rarely in the alternative surgical treatments for stress urinary incontinence (such as autologous fascia pubovaginal slings or the Burch procedure). Furthermore, when complications occur with pubovaginal slings using autologous fascia, they are easier to treat and rarely if ever result in the permanent, lifestyle altering complications mentioned above. In addition, when mesh is not involved, it is almost always possible to obtain a satisfactory result treating the complication, unlike the Gynecare TVT Exact.[42]

27. In my own experience, performing thousands of rectus fascial slings, I have never injured the bladder, urethra, ureter or any adjacent organs except for two minor urethral injuries in women

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[38] E.g., Blaivas, 2014.

[39] E.g., ETH.MESH.04048515; ETH.MESH.00130934; ETH.MESH.00400954; Isenberg Dep., 11/6/13, 461:16-530:13; 553:15-554:21; 566:9-15.

[40] E.g., Ogah, J., Cody, D. J., & Rogerson, L. (2011). Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. Neurourol Urodyn, 30(3), 284-291. doi: .1002/nau.20980; Wadie, B. S., Edwan, A., & Nabeeh, A. M. (2005). Autologous fascial sling polypropylene tape at short-term followup: a prospective randomized study. J Urol, 174(3), 990-993. doi: .1097/01.ju.0000169492.96167.fe; Garcia-Urena, 2007

[41] E.g., Blaivas, J. G., & Chaikin, D. C. (2011). Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and longterm outcome. Urol Clin North Am, 38(1), 7-15, v. doi: .1016/j.ucl.2010.12.002; Garcia-Urena, 2007.

[42] E.g., Blaivas, 2011; Blandon, R., Gebhart, J., Trabuco, E., & Klingele, C. (2009). Complications from vaginally placed mesh in pelvic reconstructive surgery. Int Urogynecol J 20, 523-531. doi: 10.1007/s00192-009-0818-9.

who had undergone multiple prior incontinence surgeries nor have we reported any nor have we reported any injuries in our case series.[43] Further, as a surgeon "of last resort" I have had the opportunity to care for at least a thousand women with complications of biologic slings, retropubic suspensions and vaginal repairs of incontinence and almost never have I seen complications of the magnitude of synthetic mesh sling complications that have become routine in my practice.

28. As a practicing surgeon, educator, academician, and editor/reviewer of scientific journals, I became aware of serious complications associated with synthetic mesh earlier than physicians in community practice. I first became aware of a death from a TVT sling approximately in 2000, but I already was including this fact in postgraduate lectures by 2002. The source of the information was first hand from the surgeon who performed the TVT. Industry (including Ethicon) representatives were present at meetings in which these complications were discussed by me and my colleagues. In addition, case reports appeared in the literature relatively soon after introduction of these devices and before clinical trials were completed. Further, complications appeared in the MAUDE database. As evidenced by Ethicon's written materials, Ethicon downplayed these complications.

29. There is almost always a time lag between what is known by Industry and physicians such as myself and community physicians. This is due to the time it takes for the dissemination of information and the withholding of information by Ethicon. Community doctors are often unable to keep up with the vast amount of and rapid changes in the scientific literature. They generally rely on manufacturers, through their sales and other representatives, to provide complete and accurate information to them. Based on my interactions with company representatives (including Ethicon), and company (including Ethicon) promotional materials, synthetic slings were invariably described as effective, quick, having few complications, and easy to learn and perform.

30. Mesh complications are significantly under-reported.[44] Additionally many, if not most, patients who experience complications do not return to their original implanting surgeons, contributing to a misperception among individual physicians that their outcomes are better than they, in fact, are.

31. The overall risk of a negative outcome after SMUS implantation surgery is $\geq$ 15%.[45] We calculated these minimum risks: revision surgery for erosion and obstruction alone, 4.1%; chronic pain, 4.1%; recurrent or persistent SUI, 5.3%; and *de novo* refractory OAB 3.9%. Of note, in patients requiring mesh removal, recurrence of SUI has been reported in 10–60% of individuals. Transobturator sling complications differed from retropubic sling complications in type and severity.

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[43] E.g., Blaivas, 2011.

[44] E.g., Deng, 2007; Anger JT, Litwin, M. S., Wang, Q., Pashos, C. L., & Rodriguez, L. V. . Complications of sling surgery among female Medicare beneficiaries. Obstetrics & Gynecology. 2007;109(3):707-14; Blaivas, 2015; Dunn, 2014

[45] Evaluating the incidence, severity and consequences of the various RP and/or TOT sling complications is a daunting task. The reasons are varied include factors such as the failure of most of the thousands of articles regarding SMUS to track complications in any meaningful way; short-term follow-up and patients lost to follow-up; new, previously unrecognized complications such as banding as a cause of dyspareunia; absence of severity descriptions of pain; different complication profiles with different slings; and failure to address outcomes (including recurrent SUI) following corrective surgeries.

32. Despite the limitations in determining the exact rate of MSUS complications, other researchers have come up with similar rates in recent literature. Barski and Deng reported that "the rate of mesh-related complications is about 15–25% and mesh erosion is up to 10% for POP and SUI repair. Mesh explantation is necessary in about 1-2% of patients due to complications."[46] Lee reported the incidence of chronic/persistent pain following MUS placement varies from 0 to 30%. The authors cited that Petri and Ashok reported on the management of 280 cases of late sling complications (RP 210 and TO 70). Compared with the retropubic MUS group, the TOT group had greater number of complications related to persistent pain (10% TVTs vs 32% TOT tapes), dyspareunia (3 vs 18%) and tape-related infections (4 vs 18%).[47] These rates are in keeping with those reported in Nature.

33. Ethicon did not adequately warn doctors and patients about the possibility of serious, chronic and lifestyle altering nature of the complications associated with its products, such as the Gynecare TVT Exact, which included chronic and debilitating pain, chronic dyspareunia and sexual dysfunction, nerve injuries/entrapment, groin and leg pain, vaginal scarring, bladder dysfunction, bladder stones, recurrent urinary or bladder infections, recurrence, refractory overactive bladder and refractory sphincteric incontinence, the need for multiple corrective surgeries that may not resolve the symptoms, the marked difficulty removing the mesh sling and that even worse complications may ensue from mesh removal, the difficulties that occurred in treating the worsening of SUI following sling removal, and others.[48] Ethicon did not adequately warn physicians about the possibility that the complications above, including erosion, could occur months or years after placement of a synthetic sling, such as the Gynecare TVT Exact.[49]

34. Ethicon did not adequately warn doctors and patients about the difficulty removing their products, such as the Gynecare TVT Exact, nor did it warn them about the suboptimal and unpredictable results when mesh excision or revision becomes warranted due to complications. Very significantly, Ethicon did not attempt to train or educate doctors on how to best treat complications when they occur.[50]

35. The design of the Gynecare TVT Exact is flawed because the product IFU does not accurately represent the nature of the inflammatory response and resulting scar tissue. Instead, the pre-2015 TVT Exact IFU states that "animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin layer of tissue, which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." Although Ethicon changed this language in January 2015 to remove the term "transient", it did not alert physicians that: (1) the

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[46] Barski and Deng 2015, 2.
[47] Lee 2015, 205.
[48] ETH.MESH.05799233
[49] E.g., *Id.*
[50] Blaivas, 2013; Unger, C., Abbot, S., Evans, J., Jallad, K., Mishra, K., Karram, M., Iglesia, C., Rardin, C., Barber, M. Outcomes following treatment for pelvic floor mesh complications. *Int Urogynecol J.* DOI 10.1007/s00192-013-2282-9.

mesh creates dense scar tissue not a "thin layer of tissue;" or (2) that the mesh is subject to degradation and weakening upon implantation.[51]

36. The design of the TVT Exact is also flawed because the product's IFU does not accurately and completely represent the nature of the potential complications that women can suffer. It simply lists an almost encyclopedic number of adverse events with a kind of equanimity that minimizes the impact on patients and conveys to the doctor the impression that although these things might occur, they are very rare. For example, it states that one or more revision surgeries may be necessary but does not mentioned the well-known fact that these operations can be very difficult to do, requires great expertise and the results are often sub optimal. Further, the IFU does not even mention the severity and life style altering nature of some of these complications.

37. In addition, the IFU incorrectly states that the TVT Exact is "tension-free." In reality, it is extremely difficult to correctly "tension" the sling. If placed even slightly too snugly, the tape may cause temporary or permanent lower urinary tract obstruction. This is compounded and the problems increase over time as the TVT Exact shrinks in a woman's body. On the other hand, if the sling is applied too loosely, incontinence will persist.

38. The pre-2015 IFU is also inadequate in that it represents complications as "transitory":

> Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.[52]

This language is not correct – the complications can be permanent, not transitory as Ethicon states. I agree with Ethicon's Associate Medical Director of Worldwide Customer Quality Meng Chen, M.D., who stated "Pardon me again, from what I see each day, these patient experiences are not "transitory" at all."[53] Although this language was deleted in January 2015 and replaced with language that reads "Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur," this language was added too many years after Ethicon was aware of the chronic nature of the problems women can experience and still does not adequately warn physicians and patients about the complications associated with the TVT Exact device.

39. Published reports on long-term outcomes of patients after mesh removal surgery are limited. Most authors of studies in this area commented on the technical difficulties encountered during mesh excision surgery and the fact that many (and in some series, most) patients require two or more surgeries; thus, even in the short term, outcomes are often suboptimal. Beyond the immediate intra-operative risks lays ahead the concern for secondary urinary incontinence and its management. At least one-third of patients undergoing sling excision surgery develop recurrent SUI. Treatment of persistent pain in patients with a SMUS is particularly challenging and has been

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[51] E.g., ETH.MESH.05588123; Barbolt Dep. 01/08/14, 409; 516-17; Hinoul Dep. 4/5/12 99:09-25; 4/6/12 518:14520:20; 6/26/13 175:1-176:17,;184:18-22; 328:10-24; Owens Dep. 9/12/2012 98:11-99:07; ETH.MESH.00870466; ETH.MESH.01218361; Holste Dep. 7/29/13 51:3-53:6; Vailhe Dep. 6/21/13 383:8-19.
[52] ETH.MESH.05799233. *Also* Weisberg dep. (8/9/13) 968:2-969:10; Robinson Dep. (9/11/13) 329:12-330:7
[53] ETH.MESH.04093125.

entirely empirical and progressive in nature. Chronic disabling pain is one of the most common indications for mesh removal[54] Barski also described the difficulty treating pain caused by mesh slings with only 28% reporting a relief of symptoms postoperatively. Particularly difficult and traumatic for the pelvic floor were the excisions of transobturator tapes, according to the Barski review.[55] Lee also described pelvic pain and dyspareunia (up to 24% following MUS) as a "most distressing and potentially irreversible complication to treat."[56] The etiology of chronic pain after MUS surgery is multifactorial. A complex interplay of factors can be causative, including synthetic material type, nerve and muscle injury, infection, con- traction, erosion or extrusion.[57]

40. Ethicon would have known about these serious complications if proper clinical trials had been performed. Appropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, like the Gynecare TVT Exact. Because of the known complications, many occurring years after the original surgery, well conducted, long term clinical trials (or a registry) would have demonstrated the extent and nature of these devastating complications.

41. The medical literature surrounding the Gynecare TVT Exact and other synthetic slings, is seriously flawed for reasons including, but not limited to, industry sponsorship, researcher bias, publication bias, industry manipulation of data, inappropriate choice of outcome variables, and lack of long-term follow-up.[58] In the Nature review, we noted the poor quality of many of the studies assessing risks of SMUS-associated complications. Deficiencies include the absence of sufficiently explicit outcome data due to the validation instruments used, the lack of long-term data, the loss of patients to follow-up, and the failure to distinguish between different products - to name a few. The poor quality of many of the studies on SMUS has been confirmed by other authors as well. Brubaker reported on missing data in two large SUI trials, TOMUS and SISTer.[59] Barski, in performing the meta-analysis on mesh complications, found no randomized trials on the surgical treatment of mesh complications and also decried the poor quality of the studies. [60]

42. Ethicon would have known about these serious complications if proper clinical trials had been performed. Appropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, like the Gynecare TVT Exact. Because of the known complications, many occurring years after the original surgery, well conducted, longterm clinical trials (or a registry) would have demonstrated the extent and nature of these devastating complications.

43. The medical literature surrounding the Gynecare TVT Exact and other synthetic slings, is seriously flawed for reasons including, but not limited to, industry sponsorship, researcher bias,

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[54] Blaivas 2015, 494.
[55] Barski and Deng 2015, p6.
[56] Lee 2015, 202.
[57] Lee 2015, 205.
[58] E.g., Blaivas, 2015; ETH.MESH.00262089; ETH.MESH.00658508; ETH.MESH.03918253
[59] Brubaker L, et al. Missing data frequency and correlates in two randomized surgical trials for urinary incontinence in women. Int Urogynecol J. 2015; 26:1155-1159.
[60] Barski D and Deng DY. Management of mesh complications after SUI and POP repair: Review and analysis of the current literature. Biomed Res Int. 2015;2015:831285, p2. Doi: 10.1155/2015/831285. [Epub 2015 Apr 20].

publication bias, industry manipulation of data, inappropriate choice of outcome variables, and lack of long-term follow-up.[61] For example, internal Ethicon documents included a contract between Ethicon and Medscand Medical A.B. in which it was to receive payment contingent upon certain predetermined study outcomes.[62] Payments to Medscand were conditioned upon the completion of studies by a predetermined date.[63] According to the agreement, Ethicon was the owner of any of work resulting from Ulmsten's studies.[64] The contract and payments were subject to Ulmsten's results regarding perioperative and postoperative complications, efficacy, and safety not varying "significantly" from Ulmsten's original publication (Int. Urogynecol J 1996-7:81-86).[65] The data used by Ulmsten and Nilsson in their initial and follow up publications was flawed and they failed to disclose the unexplained patient loss to follow up and an adverse event.[66] The 5-year follow up study also fails to report the patient loss to follow up or explain why only three of the original six centers were being included.[67] The 17-year follow up authored by Nilson also had a significant loss to follow up and only 51% of patients were evaluated in person.[68] Furthermore, a randomized study involving the TVT reported significantly lower objective success rates than those reported by Ulmsten and Nilsson.[69]

44. Many authors have signed contracts with mesh manufacturers and have acted as paid consultants for mesh manufacturers. These contracts often contain language that prevents company consultants from reporting or discussing device complications without written company approval. In some articles, these conflicts are not disclosed.[70]

45. Endorsement of these products by professional societies (e.g. the AUGS and SUFU Guidelines Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence) is biased because presents a one sided perspective. These paper cite the safety and efficacy of mesh slings, yet never even mentions the word complication. Further there is no conflict of interest statement or disclaimer despite the fact that several of the authors of the papers have financial interests with from mesh manufacturers.[71]

46. Underreporting of SMUS complications is also well-documented in the medical literature and discussed in the Nature article. Discrepancies exist between the SMUS complication rates reported by urologists from individual institutions, those reported in the literature, the (unreported)

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[61] E.g., Blaivas, 2015; ETH.MESH.00262089; ETH.MESH.00658508; ETH.MESH.03918253.
[62] E.g., ETH.MESH.08696084.
[63] E.g., ETH.MESH.08696084.
[64] E.g., ETH.MESH.08696084 at 08696116.
[65] E.g., ETH.MESH.08696084 at 08696132.
[66] E.g., ETH.MESH.00371496 at 00371587; Ulmsten data; Nilsson Int Urogynecol J 2001.
[67] E.g., *Id.*
[68] E.g., Blaivas, 2015.
[69] E.g., Albo, M. et al. Treatment success of retropubic and transobturator mid urethral slings at 24 months. J. Urol. , 2281–2287 (2012).
[70] E.g., ETH.MESH.00262089; ETH.MESH.08692936; ETH.MESH.02123291; ETH.MESH.08696084.
[71] E.g., ETH.MESH.04982735; ETH.MESH.05125268; ETH.MESH.05342590; ETH.MESH.09143435; ETH.MESH.04982748; ETH.MESH.08073794; ETH.MESH.08073801; ETH.MESH.08307690; ETH.MESH.09293114.

experience of tertiary care practices and those in the MAUDE (Manufacturer and User Facility Device Experience) database.[72] In our Nature review, we determined that approximately 88,000 removal surgeries should have been performed (based on published rates), and yet only a small fraction of such procedures are reported in the peer-reviewed literature.[73] Use of imperfect research methodologies, a lack of long-term follow up and reporting bias have been suggested as causes of these differences.[74]

47. Some authors and key opinion leaders have signed contracts with mesh manufacturers and have acted as paid consultants for mesh manufacturers. These contracts often contain language that prevents company consultants from reporting or discussing device complications without written company approval. In some articles, these conflicts are not disclosed.[75]

48. The Prolene mesh in the TVT-Exact is made from Laser Cut Mesh (LCM).[76] LCM means that the plastic mesh is cut into strips using a laser instead a cutting blade.[77] LCM is stiffer than mechanically cut mesh (MCM) which was used in the earliest versions of the TVT-R, the predecessor to the TVT Exact. An internal Ethicon memo from Becky Leibowitz to Paul Parisi and Dan Smith in late 2004 found that when the laser cut mesh was stretched it became about three times stiffer than the machine-cut TVT mesh.[78] Just four years later, in meeting notes, it is noted that there is a consensus that laser cut mesh is more rigid and stiff and that no clinical study has been done regarding the differences between laser cut mesh and mechanical cut mesh. The notes further indicate potential benefits of using mechanical cut mesh over laser cut mesh noting a lower rate of erosions, tensioning would be more similar to current products, and the edges of mechanical cut mesh might allow for an easier insertion.[79]

49. Importantly, most surgeons using the TVT family of products did not know what type of mesh (LCM or MCM) they were using.[80] Thus, there is no way for doctors to adjust tensioning differently or be aware that the mesh is stiffer, or to warn patients of an increased risk of erosions. The difference in the stretch profile between mechanically cut and laser cut mesh also led Carl G. Nilsson and Christian Falconer, two of the inventors of the original TVT,[81] and Jean de Leval, the inventor of TVT-O, to refuse to use, and question the use, of laser cut mesh.[82]

50. Moreover, use of the laser cut mesh would make them unable to rely on the original studies and data they use to tout the safety and effectiveness of the original TVT.[83] This data is something Ethicon wanted to rely on for all TVT products.[84] Additionally, laser cut mesh was never assessed

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[72] Blaivas 2015, 481-509, 484.
[73] Blaivas 2015, 481-509, 485.
[74] Blaivas 2015, 481-509, 485.
[75] E.g., ETH.MESH.00262089; ETH.MESH.08692936; ETH.MESH.02123291; ETH.MESH.08696084
[76] ETH.MESH.00576844; ETH.MESH.03546997; Smith Dep., May 15, 2014 at 48:11-17.
[77] Lamont Dep. (9/11/13) 12:13-13:14
[78] ETH.MESH.01809080; ETH.MESH.00576844.
[79] ETH.MESH.03916716
[80] ETH.MESH.09911296; ETH.MESH.09951087
[81] ETH.MESH.16416002, ETH.MESH.04048515
[82] ETH.MESH.03916716
[83] ETH.MESH.06040171; ETH.MESH.01706065
[84] Trial Testimony of Katrin Elbert, *Perry v. Luu, et al.*, (2/11/15) 3328-30

on its own in a clinical trial.[85] Finally, the rigidity of the laser cut mesh can cause a higher incidence of erosion and sexual dysfunction than mechanically cut mesh.[86]

51. It is well established in the medical and scientific literature that heavier weight, smaller pore sized mesh such as that used in the Gynecare TVT-Exact elicits a greater inflammatory and fibrotic reaction in women.[87]

52. Despite moving to a lighter weight, larger pore sized mesh for its hernia products in the late 1990's and for its pelvic organ prolapse products so as to minimize the body's inflammatory and foreign body reaction to the polypropylene devices, Ethicon continued to manufacture the Gynecare TVT Exact from the heavier weight, smaller pore sized mesh, ignoring the increased risks to patient safety and product efficacy.[88]

53. The Gynecare TVT Exact should not have been designed for permanent implantation in the human body without proper animal and human studies because the polypropylene used therein can elicit a permanent and persistent inflammatory response[89] and can create dense scar tissue.[90] Ethicon internal documents confirm it was aware of problems contemporaneously.[91]

54. The polypropylene mesh used in the Gynecare TVT Exact creates scar plate that can entrap nerves, smooth muscle, and striated muscle and causes other tissue abnormalities.[92] Pore size, density, weight and surface area are all factors involved in scar plate formation.[93] This increased scar plate formation has adverse clinical consequences in women, including distortion of the pelvic

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[85] ETH.MESH.03941617

[86] ETH.MESH.00294195; ETH.MESH.03916716; ETH.MESH.01706065; ETH MESH 03923121

[87] E.g., Klinge U, Junge K, Stumpf M, Ap AP, Klosterhalfen B. Functional and morphological evaluation of a lowweight, monofilament polypropylene mesh for hernia repair. Journal of biomedical materials research; 63(2):129-36; Klosterhalfen, 2005.

[88] E.g., ETH.MESH.07455220; ETH.MESH.09275875; ETH.MESH.02268619; ETH.MESH.02589032; ETH.MESH.01264260; Smith Dep. (2/3/2014) 723:9-724:6, 829:16-829:19; Burkley Dep. (5/22/13) 184:17-24

[89] E.g., Klinge , 1998 (Shrinking):965-9; Clave, A., Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants, I Urogynecol J, 2010 21:261-270; Klinge U, Klosterhalfen B, Muller M, Schumpelick V, "Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias,"; Eur J Surg, 1998 (164:951–960); Klostherhalfen,B, Junge, K, Klinge, U, "The lightweight and large porous mesh concept for hernia repair," Expert Rev. Med. Devices, 2005 2(1); Binnebosel M, von Trotha K, Jansen P, Conze J, Neumann U, Junge K, "Biocompatibility of prosthetic meshes in abdominal surgery" Semin Immunopathol, 2011 (33:235-243).

[90] E.g., Heise, C. P., & Starling, J. R. (1998). Mesh inguinodynia: a new clinical syndrome after inguinal herniorrhaphy? Journal Of The American College Of Surgeons, 187(5), 514-518; Demirer, S., Kepenekci, I., Evirgen, O., Birsen, O., Tuzuner, A., Karahuseyinoglu, S., & Kuterdem, E. (2006). The effect of polypropylene mesh on ilioinguinal nerve in open mesh repair of groin hernia. The Journal Of Surgical Research, 131(2), 175-181; Klosterhalfen, 2005; Klinge, 1998 (Shrinking).

[91] E.g., Burkley Dep. (5/22/13) 184:17-24; ETH.MESH.05588123

[92] E.g., Heise, 1998; Demirer, 2006; Klosterhalfen, 2005; Vervest, H., Bongers, M. & van der Wurff, A. Nerve injury: an exceptional cause of pain after TVT. Int. Urogynecol. J. Pelvic Floor Dysfunct. 6, 665–667 (2006); Iakovlev V., M. G., Blaivas J. (2014). "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert [Abstract]." International Continence Society Meeting Annual Meeting; ETH.MESH.01264260.

[93] E.g., Iakovlev, 2014; ETH.MESH.01264260

anatomy, chronic pain, dyspareunia and/or sexual impairment, bladder and/or bowel dysfunction and other complications. These forces can act on the entire structure of the Gynecare TVT Exact.[94]

55. The polypropylene mesh used in the Gynecare TVT Exact shrinks unpredictably and asymmetrically, influenced by individual response, bacterial contamination, anatomical location, and time.[95] Because of and the unpredictable amount of shrinkage, it is not possible for the surgeon to determine the proper amount of tension to apply and there is no procedure that is really reliably "tension-free". The consequences of mesh shrinkage are very significant, resulting in pain, dyspareunia, urinary symptoms, and other complications.

56. In the Nature paper, we discussed the mechanisms for mesh-related complications. These include inflammatory reactions, fibrosis, deformation, nerve entrapment, degradation, shrinkage/contraction, migration, and stiffening. These material features of polypropylene mesh and their relationship to mesh complications are discussed in my expert report. Numerous recent peer-reviewed articles have confirmed the contribution of these properties into the mechanisms of mesh-related symptoms for patients.

57. Degradation was reported in papers by Iakovlev et. al and Imel et. al on the in vivo degradation of transvaginally implanted polypropylene products. Degradation progresses over time and results in clinically significant embrittlement, loss of flexibility mesh stiffening and deformation.[96,97] Bendavid reported on the mechanism of hernia mesh repair pain. This new clinical syndrome, characterized by slow onset, relentless progression, and uncompromising lack of response to treatment, was attributed to nerve entrapment incased in dense scar tissue. According to the author, the pores of mesh need to be viewed as "mini-compartments" of biological tissue where the vasculature, nerves and their receptors are exposed to potential mechanical and chemical factors: scarring, entrapment, compression, tugging, deformation, contraction, hypoxia/acidosis, inflammation and edema.[98] In another study by Bendavid et. al, a marked increase in nerve density trapped in scar was observed in patients who had mesh-related pain, regardless of the surgical technique or surgical location.[99] Testing by Lee also discussed the mechanisms of chronic pain after MUS surgery, describing a "complex interplay of factors [that]

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[94] E.g., Blaivas, J. G., et al. (2015). "Safety considerations for synthetic sling surgery." Nat Rev Urol

[95] E.g., Klinge, 1998 (Shrinking); Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstetrics and gynecology. 2010;115(2 Pt 1):325-30; Mamy L, Letouzey V, Lavigne JP, Garric X, Gondry J, Mares P, et al. Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011;22(1):47-52; Letouzey V, Huberlant S, Lavigne J, Mares P, Garric X, De Tayrac R. Is polypropylene mesh coated with antibiotics is efficient to prevent mesh infection and contraction in an animal infectious model? [Abstract]. 37th Annual Meeting of the International Urogynecological Association. 2012:193; Jacquetin B, Cosson M. Complications of vaginal mesh: our experience. Int Urogynecol J Pelvic Floor Dysfunct. 2009;20(8):893-6; Garcia-Urena MA, Vega Ruiz V, Godoy A, Baez Perea JM, Marin Gomez LM, Carnero Hernandez FM, et al. Differences in polypropylene shrinkage depending on mesh position in an experimental study. Am J Surg. 2007;193(4):538-42

[96] Iakovlev VV, et al. Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted form patients. 2015:00B:000-000, p10.

[97] Imel A, et al. In vivo oxidative degradation of polypropylene pelvic mesh. Biomaterials. 2015 Dec;73:131-41, 132.

[98] Bendavid R, et al. Mesh-related SIN syndrome. A surreptitious irreversible neuralgia and its morphologic background in the etiology of post-herniorrhaphy pain. Int J Clin Med. 2014; 5:799-810, 799.

[99] Bendavid R, et al. A mechanism of mesh-related post-herniorrhaphy neuralgia. Hernia. 2015 Nov 23, p6. [Epub ahead of print].

can be causative, including synthetic material type, nerve and muscle injury, infection, contraction, erosion or extrusion."[100]

58. Questions have been raised in the peer-reviewed literature regarding the carcinogenic potential for transvaginally placed polypropylene mesh. We addressed this concern in our Nature review. These carcinogenic effects, leading to the development of sarcomas, have been studied in animal models. The basic research and clinical data suggest that implantation of polypropylene mesh might increase the risk of sarcoma. If a risk is present in humans, it is likely to be very low. Mutagenic effects, in general can take many years to accumulate and then a long period to cause a neoplasm. Detecting any oncogenic effects of SMUS implants would require a large cohort of patients with the same type of implant, and these patients would have to be followed up for a sufficiently long period of time, most likely at least 15 years. [101] However, a recent case of clear cell carcinoma associated with an eroded polypropylene sling was reported November, 2015 in the International Urogynecology Journal.[102] A second case of squamous cell carcinoma associated with a midurethral sling was reported at the same time. In an accompanying editorial in the same journal issue, Goldman recognized that a cause-and-effect pattern could be concerning and recommended vigilance.[103] This is new information that supports my opinions that patients who receive mesh products should be monitored closely over a long-term period.

59. I have reviewed the Material Safety Data Sheet for the polypropylene used in the Gynecare TVT Exact medical device and related documents. This document states in part, under INCOMPATIBILITY, that the following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid.[104] The Gynecare TVT Exact should not have been designed using this polypropylene because many of these chemicals are routinely found in human tissue.

60. The polypropylene mesh used in the Gynecare TVT Exact degrades *in vivo*.[105] Degradation has been reported to result in stiffening of the mesh and the presence of small molecular complexes and chemical products of degradation in surrounding tissues provides an additional stimulus for the chronic inflammatory response, which causes a continuous cycle of remodeling around the mesh filaments and extension of fibrosis.[106] *In vivo* it has been well documented that mesh also

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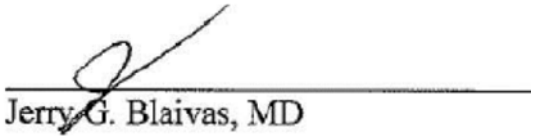
[100] Lee 2015, 205.
[101] Blaivas 2015, 481-509, 500.
[102] Lin HZ, et al. A first reported case of clear cell carcinoma associated with delayed extrusion of midurethral tape. Int Urogynecol J. 2015 Nov 20. [Epub ahead of print].
[103] Goldman HB and Dwyer. Polypropylene mesh slings and cancer: An incidental finding or association? Int Urogynecol J. 2015 Nov 19, p2. [Epub ahead of print].
[104] ETH.MESH.02026591.
[105] E.g., Jongebloed WL, Worst JF. Degradation of polypropylene in the human eye: a SEM-study. Documenta ophthalmologica Advances in ophthalmology. 1986;64(1):143-52; Coda A, Bendavid R, Botto-Micca F, Bossotti M, Bona A. Structural alterations of prosthetic meshes in humans. Hernia : the journal of hernias and abdominal wall surgery. 2003;7(1):29-34; Costello CR, Bachman SL, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene hernia meshes. Journal of biomedical materials research Part B, Applied biomaterials. 2007;83(1):44-9; Clave , 2010; Sternchuss G, Ostergard DR, Patel H. Post-Implantation Alterations of Polypropylene in the Human. J Urol. 2012;188(1):27-32
[106] E.g., Iakovlev, 2014; Junge, 2001; Blaivas, 2015.

stiffens.[107] Dr. Iakovlev and I have recently published an abstract in a peer-review journal that describes mesh hardening, degradation, deformation, and nerve/muscle entrapment from a histological standpoint and how these findings relate to pain and other mesh complications.[108] I incorporate the findings in that article into this report.

61. Ethicon's own internal document support my opinion that polypropylene mesh degrades in the body.[109]

All opinions are given to a reasonable degree of medical certainty. I reserve the right to amend or supplement this report if additional information becomes available. I also reserve the right to adopt all of my opinions in the other reports that I have submitted for the Wave 1 cases.

This 1st day of February, 2016.



Jerry G. Blaivas, MD

III. FACTS OR DATA CONSIDERED IN FORMING OPINIONS

In addition to the references included herein, an Index is attached hereto and by reference made a part hereof. Please see **Exhibit "C"** attached.

IV. COMPENSATION

Dr. Blaivas' Fee Schedule is attached hereto and by reference made a part hereof. Please see **Exhibit "B"** attached.

V. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FOUR YEARS

Merjem Delija v. Neil Sayegh, etc.; index no. 14449/2003

Jose Cuevas v. the Mount Sinai medical Center; Index no. 0017209/2004

Randy Smith, et al. v. Andrew Chan, M.D., et al.; Index No. 024786/2009

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Katelyn Vercher, et al. v. Chiari Institute, et al.; 2:09-cv-01751-AKT

Lisa Marie Fontes, et al. v. American Medical Systems, Inc.; 2:12-CV-02472

Debbie Jilovec, et al., v. American Medical Systems, Inc.; 2:12-CV-05561

Joann Serrano, v. American Medical Systems, Inc.; 2:12-CV-3719

Mary Weiler, et al. v. American Medical Systems, Inc.; 2:12-CV-05836

Carolyn F. Smothers v. Boston Scientific Corp.; 2:12-cv-08016

Katherine L. Hall v. Boston Scientific Corp.; 2:12-cv-08186

Julia Wilson v. Boston Scientific Corp.; 2012-02626

Ronda Orozco, et al., v. Boston Scientific Corp.; 2012-03068

Maria Cardenas v. Boston Scientific Corp.; 2012-02912

Diane Albright v. Boston Scientific Corp.; 2012-00909

Jo Huskey, et. al v. Ethicon, Inc.; 2:12-cv-05201

Tonya Edwards, et. al v. Ethicon, Inc.; 2:12-cv-09972

Exhibit A

Curriculum Vitae

Name: Jerry G. Blaivas, MD

Office Address:
445 East 77th Street
New York, NY 10075
Tele: (212) 772 3900

Citizenship: United States of America

Licensure: New York #144945, January 1981

Specialty Certification: American Board of Urology, 1978

Education:
Tufts University School of Medicine M.D., 1968
Tufts College, B.A., 1964

Post Graduate:

Intern, General Surgery:
Boston City Hospital
Boston, MA
1968 - 1969

Resident, General Surgery:
Boston City Hospital
Boston, MA
1969 - 1971

Resident, Urology:
Tufts-New England Medical Center
Boston, MA
1973 - 1976

Military: Major, United States Army
(Active Duty)
Department of Orthopedics
Walson Army Hospital
Fort Dix, NJ
1971-1973

Faculty Appointments:

Adjunct Professor of Urology
SUNY Downstate Medical School
Brooklyn, NY
2008 - present

Clinical Professor of Urology

Weill Medical College of Cornell University
New York, NY
1993 - present

Professor of Clinical Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1989 - 1993

Vice-Chairman, Department of Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1987 - 1993

Director, Neurourology
College of Physicians & Surgeons
Columbia University
New York, NY
1981 - 1993

Associate Professor of Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1981 - 1989

Associate Professor of Urology
Tufts University School of Medicine
Boston, MA.
1979 - 1981

Assistant Professor of Urology
Tufts University School of Medicine
Boston, MA.
1976 - 1979

Hospital and University
Administrative Appointments:

Chief of Urogynecology
Attending Surgeon (Urology)
Lenox Hill Hospital
New York, NY
1999 - 2007

Attending Surgeon (Urology)
The New York Presbyterian Hospital
New York, NY
1993 - present

Attending Urologist
The Presbyterian Hospital
New York, NY
1992 - 1993

Director, Neurourology Laboratory
The Presbyterian Hospital
New York, NY
1981 - 1993

Associate Attending Urologist
The Presbyterian Hospital
New York, NY
1981 - 1992

Chief of Urology
Helen Hayes Hospital
West Havestraw, NY
1987 - 1993

Assistant Surgeon
New England Medical Center
Boston, Massachusetts
1976 - 1981

Director, Urodynamics Laboratory
New England Medical Center

Boston, MA
1976 - 1981

Consultant in Urology
Massachusetts Rehabilitation Hospital
Boston, MA 1977 - 1981

Consultant in Urology
Braintree Hospital
Braintree, MA 1977 - 1981

Attending Physician, Surgical Service
Boston Veterans Administration Medical Center
Boston, MA
1977 – 1981

Professional Societies:

American Association of Genitourinary Surgeons
American Board of Urology
American College of Surgeons
American Urogynecologic Society
American Urologic Society, New York Section
American Urological Association
Chilean Urologic Society, Honorary Member
International Continence Society
Massachusetts Medical Society (1973 - 1981)
National Board of Medical Examiners
New York Academy of Medicine
Societe Internationale d'urologie
Society for Urodynamics and Female Urology
Society of Pelvic Surgeons
Society of University Urologists

Honors and Awards:

Victor A. Politano Award, American Urological Association, 2009

Jerry G. Blaivas Honorary Lectureship, Society of Urodynamics and Female Urology, established 2007

Continence Care Champion, National Association For Continence, 2005

Pfizer-American Urological Association Visiting Professor Award, 2004

The Best Clinical Study for the Year 2000.
Society for Urodynamics and Female Urology, 2000

Lifetime Achievement Award
Society for Urodynamics and Female Urology, 1999

Brantley Scott M.D. Award.
American Foundation for Urologic Disease, 1999.

J. Marion Sims Award
American Uro-Gynecologic Society, 1993

Best Doctors in America, 1992-present

Best Doctors in New York, 1992-present

Zimskind/Kendall Award
Urodynamic Society, 1985

First Prize for Research
Annual Meeting of the International
Continence Society, Leiden, 1982

Winner, Team Debate
Joint Meeting of the International
Continence Society and the Urodynamic
Society, Los Angeles, 1980

Commendations Medal
United States Army, 1973

Sword and Shield Honor Society
Tufts College, 1965

Hospital and University Committees:

Executive Committee
Department of Urology
College of Physicians & Surgeons
Columbia University, 1981-1993

Chairman, Quality Assurance Committee
Department of Urology
Columbia Presbyterian Medical Center
1986 - 1991

Committee on Computer Development for Medical Applications, The Presbyterian Hospital
1985 - 1993

Medical Evaluation Committee
Columbia Presbyterian Medical Center
1985 - 1987

Human Investigation Committee
Department of Urology
Columbia Presbyterian Medical Center
1981 - 1993

Chairman, Patient Care Committee
The Presbyterian Hospital
1981 - 1986

Executive Committee
Tufts University School of Medicine
1978 - 1981

Doctor's Office Committee
Columbia-Presbyterian Medical Center
1988 - 1993

Professional Committees:

Executive Committee
Society for Urodynamics and Female Urology
1999-present

Chairman, Voiding Dysfunction Committee
American Urological Association
1996-2000

Advisory Board Member

New York Menopause Center
1996 - 2000

Bladder Health Council
American Foundation for Urologic Diseases
1996 - present

Guidelines Panel on Surgical Treatments for Female Urinary Incontinence American Urological Association
1994 - Present

Executive Committee
Urodynamics Society
1993-1999

Chairman New Technology Council
American Urological Association
1993 - 1997

Guest Examiner
American Board of Urology
1992 - 1996

President
Urodynamic Society
1992 - 1993

Member, BPH Guidelines Panel
Agency for Health Care & Policy Review
1989 - 1996

Technical Advisor
Incontinence Guideline Panel
Agency for Health Care & Policy Review
1989 - 1996

Practice Parameters & Guidelines Committee
American Urological Association
1991 - 1998

Member, Terminology Committee

American Urological Association
1991 - 1993

Chairman, Biomedical Engineering Committee
American Urological Association
1990 - 1993

Vice-Chairman, New Technology Committee
American Urological Association
1990 - 1993

Vice President
Urodynamic Society
1989 - 1991

Examination Committee
American Board of Urology
American Urological Association
1989 - 1993

Protocol Committee
Measurement Committee
AUA Cooperative BPH Study
1989 - 1993

Member, ad hoc Committee on Female Urology
American Urological Association
1988 - 1993

Advisory Board, Continence Program for Women
University of Virginia
1988 - 1996

Program Committee, Annual Meeting of the
American Urological Association
1988 - 1995

Patient Management Technology Committee
National Multiple Sclerosis Foundation
1987 - 1991

Secretary, Urodynamic Society
1986 - 1989

National Metric Council - Representative from the
American Urological Association
1986 - 1991

Chairman, Urology Sub-Committee
American Society for Testing and Materials
1986 - 1991

Co-Chairman, Annual Urodynamic Society Meeting
1985

Program Committee, Combined Meeting of the
International Continence Society and the
Urodynamic Society
1985

Vice-Chairman, Urology Sub-Committee
American Society for Testing and Materials
1985 - 1986

Program Committee, Annual Meeting of the
American Urological Association
1984 - 1986

Standardization Committee
International Continence Society
1983 - 1991

Medical Advisory Board, New York Chapter
National Multiple Sclerosis Foundation
1983 - 1991

Member-at-large
Executive Committee, Urodynamic Society
1982 -1984

Program Chairman
Annual Urodynamic Society Meeting, Boston

1981

Chairman, Nomenclature Committee
Urodynamic Society
1980 -1985

Education Committee
National Multiple Sclerosis Foundation
1980 - 1990

Neurophysiology Committee
Urodynamic Society
1980 - 1986

Program Committee, Combined Meeting of the
International Continence Society and the
Urodynamic Society
1980

Biomedical Engineering Committee
American Urological Association
1980 - 1993

Chairman, Task force on Urodynamic Procedures
Urodynamic Society
1980 – 1984

Editorial Positions: Editor-in-Chief, Neurourology and Urodynamics
1981 - 2007

Editorial Boards: Neurourology & Urodynamics 1981 - present
Contemporary Urology 1998 - 2007
International Urogynecology Journal 2002 - present

Reviewer: British Journal of Urology
International Urogynecology Journal
Journal of Urology
Urology
Obstetrics & Gynecology
The New England Journal of Medicine
American Journal of Physiology

Brain
Neurology

Consulting Committee: Urologia Integrada y de Investigacion

Previous Grant Support:

Smith Kline Beecham 1993 - 1995	Effects of once daily dosing with two dose levels of epristeride or placebo on the voiding detrusor pressure in patients with bladder outflow obstruction due to benign prostatic hyperplasia.
Eli Lilly 1993 - 1995	Duloxetine vs. placebo in patients with urinary incontinence - assessment of subjective & objective parameters. $92,500
American Foundations Of Urologic Diseases Scholar Award (Faculty Sponsor) 1988 - 1990	Parameters of Detrusor Contractility $50,000
National Multiple Sclerosis Society 1977 – 1978	The Diagnosis, Treatment and National History of Voiding Disturbances in Multiple Sclerosis Grant # RG1108-A-1 $78,418
National Multiple Sclerosis Society 1978 – 1980	The diagnosis, treatment and national history of voiding disturbances in multiple sclerosis. Grant # RT1108-B-2 $113,915
Merrell Research Center 1978	Effect of Oral Candicidin on on Benign Prostatic Hypertrophy, $52,000
Smith, Klein & French 1982	Dose Range Study of Phenoxybenzamine in Benign

	Prostatic Hypertrophy $27,000
Eastern Paralyzed Veterans 1983 - 1984 Grant $100,000	Neuro*Urology* Fellowship
Eastern Paralyzed Veterans 1984 - 1985 Training Grant $17,000	Neurourology Nurse
Roerig Pharmaceuticals 1984 - 1985	Geocillin in the Treatment of Recurrent Urinary Tract Infections Study # 83-R-003 $25,000
Roerig Pharmaceuticals 1985-1986	Geocillin for the Treatment of Bacterial Prostatitis in Patients with Multiple Sclerosis or Spinal Cord Injuries with Associated Dysfunctional Urinary Bladders Study # 84-R-014 $18,000
American Federation For Aging (AFAR) 1987 - 1988	Urodynamics of Aging AFAR CU50384501 $16,000
Embassy Arab Republic of Egypt Cultural and Educational Bureau Peace Fellowship Program	Bladder Outlet Obstruction PF # 2436 - $17,000
Spinal Cord Research Foundation 1989 – 1990	Parameters of Bladder Contractility in an In-vitro Rabbit Bladder Model, $19,200
National Multiple 1988 - 1991	Neurourodynamic Evaluation Sclerosis Foundation of Multiple Sclerosis Grant # RG1997-A-4

$116,682

PUBLICATIONS

Articles in Peer Review Journals:

1. **Blaivas JG**, Pais, VM, Spellman, RM. Chemolysis of Residual Stone Fragments After Extensive Surgery for Staghorn Calculi. *Urology* 6:680-6, 1975.

2. **Blaivas JG**, Pais VM, Retik AB. Paraurethral Cysts in the Female Neonate. *Urology* 7:504-7, 1976.

3. **Blaivas JG**, Previte SR, Pais VM. Idiopathic Pelviureteric Varices. *Urology* 9:207-1, 1977.

4. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. A New Approach to Electromyography of the External Urethral Sphincter. *J Urol* 117:773-7, 1977.

5. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. Changing Concepts in the Urodynamic Evaluation of Children. *J Urol* 117:778-3, 1977.

6. **Blaivas JG**, Labib, KB.Urinary Retention in the Female: Complete Urodynamic Evaluation. *Urology* 10:383, 1977.

7. Rao CN, **Blaivas JG**. Primary Renal Artery Dissecting Aneurysms, A review. *J Urol* 118:716-9, 1977.

8. Labib KB, Bauer SB, **Blaivas JG.** External Sphincter Electromyography in a Comprehensive Urodynamic Evaluation. *Archives Phys Med & Rehab*, 58:521, 1977.

9. **Blaivas JG**, Labib KB, Scott RM. Urodynamic Evaluation as neurologic test of Sacral Cord Function. *Urology* 9:682,1979.

10. **Blaivas JG**, Bhimani G, Labib KB. Vesicourethral Dysfunction in Multiple Sclerosis. *J Urol* 122:342-7,1979.

11. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Failure of Bethanechol Denervation Supersensitivity as a Diagnostic Aid. *J Urol* 123:199,1980.

12. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Cystometric Response to Propanetheline in Detrusor Hyperreflexia: Therapeutic Implications. *J Urol* 124:259,1980.

13. **Blaivas JG**. Management of Bladder Dysfunction in Multiple Sclerosis. *Neurology* 30(2):12,1980.

14. **Blaivas JG**, O'Donnell TF, Gottlieb P, Labib KB. Comprehensive Laboratory Evaluation of Erectile Dysfunction. *J Urol* 124:201,1980.

15. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia, *J Urol* 125:542-4,1981.

16. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia: A detailed EMG study. *J Urol* 125:545-8,1981.

17. **Blaivas JG**, Fisher DM. Combined Radiographic and Urodynamic Monitoring: Advances in Technique. *J Urol* 125:693-4,1981.

18. **Blaivas JG**, Zayed AAH, Labib KB. The Bulbocavernosus Reflex in *Urology*: A Prospective Study of 299 Patients. *J Urol* 126:197-9,1981.

19. **Blaivas JG**. The Neurophysiology of Micturition. *J Urol* 127:958-3,1982.

20. **Blaivas JG**, Awad SA, Bissada N, Khanna OP, Krane RJ, Wein AJ, et al. Urodynamic Procedures: Recommendations of the Urodynamic Society. 1. Procedures Which Should be Available for Routine Urologic Practice. *Neurourol Urodyn* 1:51-5,1982.

21. Sant GR, Heaney JA, Parkhurst EC, **Blaivas JG**. Obstructive Uropathy. A Potentially Serious Complication of Reconstructive Vascular Surgery. *J Urol* 129:16-2,1982.

22. Barbalias GA, **Blaivas JG**. Neurourologic Implications of the Pathologically Open Bladder Neck. *J Urol* 129:780-3,1983.

23. Zinner NR, Susset, J, Coolseat BRLA, Griffiths D, Jonas U, Sterling AM, **Blaivas JG**, et al. Great Debate Resolved: The Urethral Closure Pressure Profile Should be Used For Diagnosis and Management of Female Stress Incontinence. *Neurourol Urodyn* 2:81-99,1983.

24. **Blaivas JG**, Barbalias GA. Characteristics of Neural Injury After Abdominal Perineal Resection. *J Urol* 129:84-7,1983.

25. Sant G, **Blaivas JG**, Meares EM. Hemiacidrin Irrigation in the Management of Struvite Calculi: Long Term Results. *J Urol* 130:1048-50,1983.

26. Norlen LJ, **Blaivas JG**, Gable H. Cystopathy in Patients With Severe Diabetic Nephropathy. Diabetic Nephropathy,1983.

27. **Blaivas JG.** Sphincter Electromyography. *Neurourol Urodyn* 2:269-88,1983.

28. Katz GP, **Blaivas JG.** A Diagnostic Dilemma: When Urodynamic Findings Differ From the Clinical Impression. *J Urol* 129:1170-4,1983.

29. Norlen LJ, **Blaivas JG**, Grodin W, Lundberg JM. Contractile Effect of Substance P on the Canine Urinary Bladder In Vivo. *Neurourol Urodyn*, 2:323-7,1983.

30. **Blaivas JG**, Barbalias GA. Detrusor External Sphincter Dyssynergia in Men With Multiple Sclerosis: An Ominous Urological Condition. *J Urol* 131:91-4,1984.

31. Barbalias GA, **Blaivas JG**, Klauber G. Critical Evaluation of the Crede Maneuver: A Urodynamic Study of 207 Patients. *J Urol* 131:91-4,1984.

32. **Blaivas JG**. Multichannel Urodynamic Studies. *Urology* 23:421-38,1984.

33. Sawzcuk I, **Blaivas JG.** Successful Surgical Treatment of Giggle Incontinence. *Neurourol Urodyn* 3:63,1984.

34. **Blaivas JG.** Urodynamic Diagnosis of Primary Bladder Neck Obstruction. World *J Urol* 2:191,1984.

35. Oliver LM, **Blaivas JG**, McGuire E, Susset, J. Functional Vaginal Electrical Stimulation (FVES) for the Treatment of Frequency and Incontinence in Women. Proceedings of the Urodynamic Society, p47,1984.

36. **Blaivas JG**, Salinas J. Type III Stress Urinary Incontinence: The Importance of Proper Diagnosis and Treatment. *Surgical Forum* 35:472,1984.

37. **Blaivas JG.** Salinas J., Katz P. Role of Urodynamic Testing in the Evaluation of Subtle Neurourological Lesions. *Neurourol Urodyn* 4:211-8,1985.

38. Abrams P, **Blaivas JG**, Stanton SL, Andersen J, Fowler CJ, Gerstenberg T, et al. Sixth Report on the Standardisation of Terminology of Lower Urinary Tract Function. Procedures Related to Neurophysiological Investigations: Electromyography, Nerve Conduction Studies, Reflex Latencies, Evoked Potentials and Sensory Testing. The International Continence Society on Standardisation of Terminology, New York, *Scand J Urol Nephrol* 20:161-4,1986

39. Norlen L, **Blaivas JG**. Unsuspected Proximal Urethral Obstruction. *J Urol* 135:972-6,1986.

40. Salinas J, Berger Y, De La Rocha RE, **Blaivas JG**. Urologic Evaluation in the Shy- Drager Syndrome. *J Urol* 135:741-3,1986.

41. Abrams P, Andersen JT, **Blaivas JG**, Stanton SS. Sixth Report of the Standardization of Terminology of Lower Urinary Tract Function: Procedures Related to Neurophysiologic Investigations. *Neurourol Urodyn* 5:373-9,1986.

42. Axelrod SA, **Blaivas JG**. The Distinction Between Poor Detrusor Contractility and Bladder Outlet Obstruction. Proceedings of the International Continence Society. Boston, 1986.

43. Axelrod SA, **Blaivas JG**. Bladder Neck Obstruction in Women. *J Urol* 137:497-9,1987.

44. BergerY, **Blaivas JG**, De La Rocha RE, Salinas JM. Urodynamic Findings in Parkinson's Disease. *J Urol* 138:836-8,1987.

45. Abrams P, **Blaivas JG**, Stanton SL, Andersen J, Fowler CJ, Gerstenberg T, Murray K. Sixth Report on the Standardization of Terminology of Lower Urinary Tract Function. Procedures Related to Neurophysiological Investigations: Electromyography, Nerve Conduction Studies, Reflex Latencies, Evoked Potentials and Sensory Testing. The International Continence Society, *Br J Urol* 59:300-4,1987.

46. **Blaivas JG**, Olsson CA. Stress Incontinence: Classification and Surgical Approach. *J Urol* 139:727-1,1988.

47. Sarky MS, **Blaivas JG**. Functional Types of Prostatic Obstruction. *Neurourol Urodyn* 7:221-2,1988.

48. Sarky MS, **Blaivas JG**. Low-Pressure Low-Flow Syndromes. A Computer Based Classification on Functional Basis. *Neurourol Urodyn* 7:225-6,1988.

49. Sarky MS, **Blaivas JG**, Schussler G. Bladder Outlet Conductance: Evolution, Normal and Obstructive Patterns. *Neurourol Urodyn* 7:223-4,1988.

50. **Blaivas JG.** Pathophysiology and Differential Diagnosis of Benign Prostatic Hypertrophy. *Urology* 32:supp5-11,1988.

51. Abrams P, **Blaivas JG**, Stanton SL. Andersen JT. The Standardisation of Terminology of Lower Urinary Tract Function. *Neurourol Urodyn* 7:403-26,1988.

52. Kaplan SA, **Blaivas JG.** Diabetic Cystopathy. *J Diabet Complic* 2:133-9,1988.

53. **Blaivas JG**. Vaginal Flap Urethral Reconstruction: An Alternative to Bladder Flap Neourethra. *J Urol* 141:542-5,1989.

54. Kaplan SA, Brown WC, **Blaivas JG.** Parameters of Detrusor Contractility: Effects of Hysteresis and Bladder Volume in an In-Vitro Whole Rabbit Model. Surgical Forum, Volume XL 665-6,1989.

55. Kaplan SA, **Blaivas JG**, Brown WC, Schuessler G. Parameters of Detrusor Contractility: The Effect of Bladder Volume and Outlet Resistance on Qmax, Power and Work in In-Vitro Whole Rabbit Model. *Neurourol Urodyn* 8:375-6, 1989.

56. **Blaivas JG**. Diagnostic Evaluation of Urinary Incontinence.*Urology* 36:4,1990.

57. BergerY, Salinas JN, **Blaivas JG.** Urodynamic Differentiation of Parkinson's Disease and the Shy Drager Syndrome. *Neurourol Urodyn* 9:117-1,1990.

58. BergerY, **Blaivas JG**, Oliver L. Urinary Dysfunction in Transverse Myelitis. *J Urol* 144:103-5,1990.

59. **Blaivas JG**. Surgical Treatment of Urinary Incontinence in 223 Consecutive Women. *Neurourol Urodyn* 9:401-2,1990.

60. Chancellor MB, Otter MW, Kaplan SA, **Blaivas JG**. A New Method of Measuring Uroflow in the Rat Bladder. *Neurourol Urodyn* 9:391-2,1990.

61. **Blaivas JG.** Diagnostic Evaluation of Incontinence in Patients with Neurourologic Disease*, J Am Geriatr Soc* 38:306-0,1990.

62. Kaplan SA, **Blaivas JG**, Brown WC, Levin RM. Parameters of Detrusor Contractility: The Effect of Hysteresis, Electrical Stimulation and Bladder Volume in an In-Vitro Whole Rabbit Model. *Neurourol Urodyn* 10:53-9,1991.

63. **Blaivas JG.** Diagnostic Evaluation of Incontinence. *Urology* 36:supp11-20,1991.

64. Chancellor MB, **Blaivas JG**, Axelrod S, Kaplan SA. Bladder Outlet Obstruction Versus Impaired Detrusor Contractility: The Role of Uroflow. *J Urol* 145:810-2,1991.

65. Luangkhot R, Peng B, and **Blaivas JG**. Ileocecocystoplasty for the Management of Refractory Neurogenic Bladder: Surgical Technique and Urodynamic Findings. *J Urol* 146:1340-4,1991.

66. **Blaivas JG**, Jacobs BZ. Pubovaginal Sling for the Treatment of Complicated Stress Incontinence. *J Urol* 145:1214-8,1991.

67. Kaplan SA, **Blaivas JG**, Chancellor MB. Bladder and Sphincter Behavior in Patients with Spinal Cord Injury. *J Urol* 146:113-7,1991.

68. Chancellor MB, **Blaivas JG**, Levin RM, Kaplan SA, Otter MW, Schussler G. New Method of Measuring Uroflow in the Rat Bladder. *Neurourol Urodyn* 11:123-9,1992.

69. Andersen JT, **Blaivas JG**, Cardozo L, Thuroff J. Lower Urinary Tract Rehabilitation Techniques: Seventh Report on the Standardization of Terminology of Lower Urinary Tract Function. *Neurourol Urodyn* 11:593-3,1992

70. Barry MJ, Fowler FJ, O'Leary MP, Bruskewitz RC, Holtgrewe HL, Meburst WK, AUA Measurement Committee. Correlation of the American Urological Association Symptom Index with Self-Administered Versions of the Madsen-Iversen, Boyarsky and Maine Medical Assessment Program Symptom Indexes. *J Urol* 148:1558-3,1992.

71. Chancellor MB, Kaplan SA, **Blaivas JG**. The Cholinergic and Purinergic Components of Detrusor Contractility in a Whole Rabbit Bladder Model. *J Urol* 148:906-9,1992.

72. Grino PB, Bruskewitz R, **Blaivas JG**, et al. Maximum Urinary Flow Rate by Uroflowometry: Automatic or Visual Interpretation. *J Urol* 149:339-1,1993.

73. Kaplan SA, Shabsigh R, Soldo KA, **Blaivas JG**, Olsson CA. Transrectal Hyperthermia in the Management of Men with Prostatism: An Algorithm for Therapy. *J Urol* 72:195-0,1993.

74. Chancellor MB, **Blaivas JG**, Kaplan SA, Axelrod S. Letter to the Editor Re: Bladder Outlet Obstruction Versus Impaired Detrusor Contractility: The Role of Uroflow. *J Urol* 149:378-9,1993.

75. Chaikin DC, **Blaivas JG**, et al. Behavioral Therapy for the Treatment of Refractory Interstitial Cystitis. *J Urol* 149:1445-8,1993.

76. Gardner TA, Poppas DP, Wei JT, **Blaivas JG**. Volvulus of the Ileal Conduit: A Late Complication. *J Urol* 152:948-50,1994.

77. Seaman EK, Jacobs BZ, **Blaivas JG,** Kaplan SA. Persistence or Recurrence of Symptoms after Transurethral Resection of the Prostate: A Urodynamic Assessment. *J Urol* 152:935-7,1994.

78. Santarosa RP, **Blaivas JG**. Peiurethral Injection of Autologous Fat for the Treatment of Sphincteric Incontinence. *J Urol* 151:607-1,1994.

79. **Blaivas JG.** Urinary Incontinence After Radical Prostatectomy. *Cancer* 75:7,1995.

80. Heritz DM, Romanzi LJ, **Blaivas JG.** The Surgery of Vesico-Vaginal Fistula: Early vs. Late, Abdominal vs. Vaginal Repair. *J Urol* 153:1110-3,1995.

81. Kaplan SA, Te AE, **Blaivas JG**. Urodynamics Findings in Patients With Diabetic Cystopathy. *J Urol* 153:342-4,1995.

82. Mulcahy JJ, Kirkemo, AK, Rudy DC, **Blaivas JG**, Wahle GR, et al. Efficacy and Safety of Duloxetine in Stress Incontinence Patients. *Neurourol Urodyn* 15:395-9,1996.

83. **Blaivas JG**, Heritz DM.Vaginal Flap Reconstruction of the Urethra and Vesical Neck in Women: A Report of 49 Cases. *J Urol* 155:1014-7,1996.

84. **Blaivas JG**. Obstructive uropathy in the male. *Urol Clin North Am* 23:373-84,1996.

85. **Blaivas JG**, Heritz DM. Physiological Principles for Surgical Correction of Detrusor Dysfunction. *J EndoUrology* 10:3,1996.

86. **Blaivas JG**, Appell RA, Fantl JA, Leach G, McGuire EJ, Resnick, NM, et al. Standards of Efficacy for Evaluation of Treatment Outcomes in Urinary Incontinence: Recommendations of the Urodynamic Society. *Neurourol Urodyn* 16:145-7,1997.

87. **Blaivas JG**. Discussion: A Framework for Diagnosis of Idiopathic Overactive Bladder. *Urology* 50:6A,1997.

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Books

1. Neuro*Urology* and Urodynamics: Principles and Practice, Edited by Yalla S, McGuire EM, Elbadawi A, **Blaivas JG**, New York, MacMillan Publishing Co.1988.

2. Problems in Urology: Neurourology and Its Role in Urologic Disease: Part I, **Blaivas JG**, Chancellor MB, Guest Editors, Paulson Editor-in-Chief. 6:4,1992.

3. *Practical Neurourology: Genitourinary Complications in Neurourologic Disease*, Edited by **Blaivas JG**, Chancellor MB. Butterworth-Heineman, Boston, 1995.

4. *Topics in Clinical Urology: Evaluation and Treatment of Urinary Incontinence*, Edited by **Blaivas JG**. Igaku-Shoin. New York,1996.

5. **Blaivas JG**, Chancellor MB (eds.). *Atlas of Urodynamics*, Williams and Wilkins, 1996.

6. **Blaivas JG.** *Conquering Bladder and Prostate Problems: an Authoritative Guide for Men and Women*, Plenum Publishing Corp. New York, 1998.

7. **Blaivas JG**, Lepor H, Nitti VW, Weiss JP. *Case Studies in Benign Prostatic Hyperplasia*, Isis Medical Media Ltd. 2000.

8. Flisser AJ, Weiss JP, **Blaivas JG.** Fast Facts in Neurourology and Urodynamics, In: *Urology Highlights* 2001-02, Shah J, Editor, Health Press, Ltd, Oxford, UK,

9. **Blaivas JG**, Chancellor MB, Verhaaren MR, Weiss JP (eds.). *Atlas of Urodynamics (2nd Ed.),* Wiley-Blackwell, 2007.

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11. **Blaivas, JG,** Purohit, RS, Diagnosis and Treatment of Overactive Bladder, Oxford University Press, New York, 2011

12. Weiss, JP, **Blaivas, JG,** van Kerrebroeck, PEV, Wein, AJ, Nocturia: Causes, Consequences and

Clinical Approaches, Springer, New York, 2012

VISITING PROFESSOR AND NAMED LECTURESHIPS

1. Universitas Complutensas (Madrid)
2. Scandinavian Association of Urology, 1984
3. Sociedad Chilena de Urologia, 1985
4. University of Washington
5. University of Texas (Dallas), 1990
6. Tufts University, Kamil B. Labib Memorial Lecture
7. University of Iowa
8. University of Pennsylvania, 2000
9. University of Massachusetts, Harold M. Lieberman Memorial Lecture
10. Loyola University, Roland R.Cross Visiting Professor of Urology, 1992
11. Northeastern Section of the American Urologic Section, George F. Slotkin Lectureship, 2000
12. Beth Israel Medical Center (New York)
13. Case Western Reserve University, 2001
14. University of Alabama
15. Mayo Clinic (Jacksonville)
16. Albany Medical College, 2001
17. University of Toronto, 2003
18. Canadian Urologic Association
19. University of Cincinnati, 2004
20. University of Massachusetts, 2004

21. University of Buffalo, 2004.
22. Hugh Hampton Young lecture, Mid-Atlantic Section, AUA, 2005
23. University of Vermont 2012

Jerry G. Blaivas, MD, FACS
Biographical Sketch

Dr. Blaivas is an internationally renowned urologist with over thirty years of clinical experience. He is, as well, an acclaimed academician, educator, writer and editor with an unimpeachable reputation for honesty and compassion. His clinical expertise ranges from office urology to the most complicated and difficult surgical problems. Known as a "doctor's doctor," he is considered the "doctor of last resort" by patients and doctors alike when they experience multiple failed treatments.

Dr. Blaivas is Clinical Professor of Urology at Weill Cornell Medical College, Adjunct Professor at SUNY Downstate and Attending Surgeon at New York Presbyterian Hospital and Lenox Hill Hospital. He is former Professor of Urology and Vice Chairman of the Department of Urology at Columbia University College of Physicians and Surgeons.

In addition to a widely acclaimed expertise in routine urologic conditions such as prostate problems in men, pelvic organ prolapse (dropped bladder) in women and incontinence in both sexes, Dr. Blaivas was one of the originators of urodynamics and pioneered many of the current surgical procedures to correct stress incontinence, urinary fistulas, urethral diverticulum, overactive bladder and neurogenic bladder. He is one of the few surgeons who routinely performs reconstructive surgery for prolapse and incontinence without the use of mesh and has published one of the largest series in the world on treatment of mesh complications. He has a particular interest and expertise in complex urologic problems – complications of radiation and prostate surgery, failed incontinence surgery and failed prolapse surgery.

Dr. Blaivas is former President of the Urodynamics Society and the recipient of numerous awards, including the Lifetime Achievement Award from the Society for Urodynamics and Female Urology, the Victor A. Politano Award from the American Urological Association, the F. Brantley Scott M.D. Award from the American Foundation for Urologic Disease, the J. Marion Sims Award from the American Uro-Gynecologic Society and the Paul Zimskind Award from the Urodynamic Society.

In addition, Dr. Blaivas has consistently been listed in *New York Magazine's Best Doctors* and Castle Connolly's *America's Top Doctors* and *Top Doctors: New York Metro Area* from the publications' inception in 1992 to the present.

Dr. Blaivas is the Founder of the major scientific journal *Neurourology & Urodynamics* and was Editor-in-Chief from 1982-2006. He is on the editorial board of *Contemporary Urology* and *International Urogynecology Journal* and is a reviewer for a number of other journals, including the *Journal of Urology*, *Urology*, *The New England Journal of Medicine*, and *British Journal of Urology*. He is the primary author of over 400 peer review scientific articles, book chapters and reviews and has edited seven books. He is a member of numerous professional societies, including the American Association of Genitourinary Surgeons, Society of Pelvic Surgeons, American Urological Association, American College of Surgeons, Society for Urodynamics and Female Urology, American Urogynecologic Society, and the International Continence Society.

Dr. Blaivas founded the not-for-profit organization, the Institute for Bladder and Prostate Research, which is dedicated to research relating to the lower urinary tract and female genital tract, including urinary incontinence, prostate conditions, neurogenic bladder, interstitial cystitis and genital prolapse. In addition, he is the author of a book for the lay public on bladder and prostate conditions entitled, *Conquering Bladder and Prostate Problems; an Authoritative Guide for Men and Women.*

Exhibit B

Jerry G. Blaivas, MD, FACS
Urology
445 East 77th Street
New York, NY 10075

Diplomat
American Board of Urology

Phone (212) 772-3900
Fax (212) 772-1919

November 1, 2012

Margaret M. Thompson, MD JD MPAFF
Mueller Law
404 W. 7th Street
Austin, TX 78701

Re: Dr. Blaivas' fee schedule

To whom it may concern:

Per your request, I have set forth Dr. Blaivas' fee schedule below. Please be advised that **fees are required prior to or at the time of service**.

$750 per hour for review of medical records and preparation of reports.

$7,500 for a half day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

$15,000 for a full day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

Given the nature of Dr. Blaivas' practice, he must be notified well in advance of any cancellation. Otherwise the above fee schedule will apply.

Please confirm your agreement to the above terms by signing below.

Sincerely,

Kimberly Stone

_____
Addressee ***Sign***

_____
Addressee ***Print***

Exhibit C

Clinical Literature Relied Upon by Dr. Jerry Blaivas

Document Date	Title	Primary Author	Publication
2013-00-00	Correction: Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse		N ENGL J MED 368;4:394
2012-00-00	GUIDE TO LEARNING IN FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY		
	Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multi-Center Study	Abbot, et al	Presentation Number: Paper 29
2014-01-01	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Abbott, et al	Am J Obstet Gynecol 2014;210:163.e1-8
2011-01-01	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications	Abdel-Fattah, et al	European Urology 60 (2011) 468 - 480
2006-01-01	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure	Abdel-Fattah, et al	BJU Int, 98(3), 594-598
2008-01-01	Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse	Abdel-Fattah, et al	BJOG 2008;115:22–30
	A RANDOMISED PROSPECTIVE SINGLE-BLINDED STUDY COMPARING "INSIDE-OUT" VERSUS "OUTSIDE-IN" TRANSOBTURATOR TAPES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (E-TOT STUDY); 3 YEARS FOLLOW-UP.	Abdel-fattah, et al	Poster 18
2010-01-01	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes	Abdel-fattah, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111
2010-04-12	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study	Abdel-fattah, et al	BJOG 2010;117:870—878

2010-05-18	Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence	Abdelwahab, et al	Current Urology, 4(2), 93-98
2011-01-01	Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials; a systematic review	Abed, et al	Int Urogynecol J (2011) 22:789–798
2011-01-01	Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair	Aboseif, et al	World J Urol (2011l 29:249—253
2011-00-00	Is Tissue Engineering and Biomaterials the Future for Lower Urinary Tract Dysfunction (LUTD)/Pelvic Organ Prolapse (POP)?	Aboushwareb, et al	Neurourology and Urodynamics 30:775--782 (2011j
2009-01-01	Tissue mechanics, animal models, and pelvic organ prolapse: A review	Abramowitch, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 144S (2009) S146–S158
2011-01-01	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	Abrams, et al	European Urology 60:1207-1211
2006-12-01	ACOG Committee Opinion Number 352: Innovative Practice: Ethical Guidelines	ACOG	ACOG Committee Opinion No. 352
2007-02-01	ACOG PRACTICE BULLETIN NUMBER 79: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS	ACOG	The American College of Obstetrics & Gynecology
2007-09-01	ACOG PRACTICE BULLETIN NUMBER 85: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN - GYNECOLOGISTS NUMBER 85	ACOG	The American College of Obstetricians and Gynecologists
2005-06-01	ACOG Practice Bulletin Number 63: Clinical Management Guidelines for Obstetrician-Gynecologists	Acog Committee on Practice Bulletins--Gynecology	Obstet Gynecol
2008-10-01	A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings	Agarwala N	UroToday International Journal / Vol 1 / Iss 4/
2007-01-01	Laparoscopic sacral colpopexy with Gynemesh as graft material-Experience and results	Agarwala, et al	Journal of Minimally Invasive Gynecology (2007) 14, 577–583

2014-01-01	Functinal outcomes following surgical managment of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Agnew, et al	Int Urogynecol J (2014) 25:235–239
2006-00-00	Mesh migration following repair of inguinal hernia: a case report and review of literature	Agrawal, Avill	Hernia (2006) 10: 79--82
2011-01-01	Long term patient satisfaction after suburethral sling operation for stress incontinence	Al-Omary, Atalla	Int Urogynecol J (2011) 22 (Suppl 3):
2007-01-01	Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence	Albo, et al	N Engl J Med 2007;356:2143-55
2012-12-01	Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months	Albo, et al	J Urol Vol. 188, 2281-2287
2009-00-00	Isolation of fibroblasts for coating of meshes for reconstructive surgery: differences between mesh types	Albrich, et al	Regenerative Medicine
2003-01-02	Use of Cadaveric Fascia Lata To Correct Grade IV Cystocele	Almeida,et al	International Braz J Urol Vol. 29 (1): 48-52
2011-01-01	Anterior Colporrhapy versus Transvaginal Mesh for Pelvic-Organ Prolapse	Altman, et al	N Engl J Med 2011;364:1826-36
2007-02-01	Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair	Altman, et al	Obstet Gynecol 2007;109:303–8
	INTRA- AND PERIOPERATIVE MORBIDITY FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING A TRANSVAGINAL SUTURE CAPTURING MESH DEVICE COMPARED TO TROCAR GUIDED TRANSVAGINAL MESH AND TRADITIONAL COLPORRAPHY	Altman, et al	Abstract
2007-01-01	Lower urinary tract injuries associated with the out-in transobturator tape - is cystoscopy required An Argentinean multicenter experience	Altuna,et al	Int Urogynecol J (2007) 18 (Suppl 1):
2009-01-01	Clinical and Quality-of-Life Outcomes after Autologous Fascial Sling and Tension-Free Vaginal Tape: A Prospective Randomized Trial	Amaro, et al	International Braz J Urol Vol. 35 (1):60-67
1997-01-01	Classification of biomaterials and their related complications in abdominal wall hernia surgery	Amid PK	Hernia (1997) 1:15-21

2010-01-01	Complications of polypropylene mesh in prolapse surgery	Ammembal, Radley	OBSTETRICS, GYNAECOLOGY AND REPRODUCTIVE MEDICINE 20:12, 359-364
1998-01-01	Concise review of mechanisms of bacterial adhesion to biomaterial surfaces	An, Friedman	J Biomed Mater Res (Appl Biomater) 43: 338—348
2008-01-01	Foreign Body Reaction to Biomaterials	Anderson, et al	SEMIN. IMMUNOL. 20(2): 86-100
1985-01-01	Utilization of Adipose Tissue Biopsy in Characterizing Human Halogenated Hydrocarbon Exposure	Anderson, HA	Environmental Health Perspectives
2007-01-01	Prospective Clinical Trial Comparing Obtape and DUPS to TVT: One-Year Safety and Efficacy Results	Andonian, et al	European Urology 52 (2007) 245-252
2005-01-13	Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-free Vaginal Tape (TVT): One-Year Results	Andonian, et al	European Urology 47 (2005) 537—541
2007-01-01	Complications of Sling Surgery Among Female Medicare Beneficiaries	Anger, et al	Obstet Gynecol 2007;109:707–14
2010-01-01	Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial	Angioli, et al	European Urology 58 (2010) 671-677
2009-01-01	Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence	Aniuliene R	Medicina (Kaunas) 2009; 45(8)
1986-03-22	Epistemology of Surgery	Anon	The Lancet
2009-01-01	The influence of BMI, smoking, and age on vaginal erosions after synthetic mesh repair of pelvic organ prolapses. A multicenter study	Araco, et al	Acta Obstetricia et Gynecologica. 2009; 88: 772—780
2008-01-24	TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence	Araco, F. et al	Int Urogynecol J (2008) 19:917–926
2012-01-01	Complications from the Placement of a Tension-Free Suburethral Sling Using the Transobturator and Retropubic Methods for Treatment of Female Urinary Incontinence	Arrabal-Polo, et al	Urologia Internationalis
2003-01-01	Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire-based study	Arunkalaivanan, Barrington	Int Urogynecol J (2003) 14: 17—23

	SINGLE-INCISION MIDURETHRAL TAPE (OPHIRA) VS TRANSOBTURATOR TAPE (OBTRYX): PROSPECTIVE COMPARATIVE STUDY- 2 YEAR FOLLOWUP	Arunkalaivanan, et al	Abstract 245
2009-01-01	Efficacy and safety of transobturator tape (Obtryx) in women with stress urinary incontinence and intrinsic sphincter deficiency	Arunkalaivanan,et al	Presentation 778
2008-00-00	Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review	Atassi, et al	Arch Gynecol Obstet, 277(2), 161-164
2013-01-01	Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail?	Athanasiou, et al	Int Urogynecol J
2009-01-01	MIXED URODYNAMIC INCONTINENCE: TVT or TVT-O?	Athansiou, et al	Int Urogynecol J (2009) 20 (Suppl 2):S73–S239
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh For the Repair of Pelvic Organ Prolapse	AUA	American Urological Association
2012-04-01	ADULT URODYNAMICS: AUA/SUFU GUIDELINE	AUA	American Urological Association Education and Research, Inc.
2009-01-01	Guideline for the Surgical Management of Female Stress Urinary Incontinence 2009 Update	AUA	
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence	AUA	
2013-01-01	Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse	AUGS	Female Pelvic Medicine & Reconstructive Surgery, 19, 2
2011-07-01	AUGS Response FDA Safety Communications	AUGS	American Urogynecologic Society
	Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders	AUGS	American Urogynecologic Society
2011-09-09	AUGS statement September 8-9, 2011	AUGS	AUGS
2012-01-01	Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse	AUGS	Female Pelvic Medicine & Reconstructive Surgery Volume 18, Number 4
2014-01-01	Committee Opinion: Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment	AUGS and ACOG	Female Pelvic Medicine & Reconstructive Surgery 20; 5: 248 - 251
	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS, SUFU	

2014-01-03	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS-SUFU	
2009-01-01	Do novo stress incontinence and pelvic muscle symptons after transvaginal mesh repair	Aungst,et al	Am J Obstet Gynecol 2009;201:73.e1-7
2006-01-01	Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation	Babalola, et al	Int Urogynecol J (2006) 17: 418—421
2004-00-00	Cystocele repair by vaginal approach with a tension-free transversal polypropylene mesh	Bader, et al	Gynécologie Obstétrique & Fertilité 32 (2004) 280--284
2005-10-01	Severe Mesh Complications Following Intravaginal Slingplasty	Baessler, et al	Obstet Gynecol 2005;106:713–6)
2006-01-01	Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits	Baessler, Maher	Curr Opin Obstet Gynecol 18:560–566
2006-01-01	Principles of Polymer Science, 2nd Edition	Bahadur, Sastry	
2009-01-01	Review of synthetic mesh-related complications in pelvic floor reconstructive surgery	Bako, Dhar	Int Urogynecol J (2009) 20:103-111
	LONG-TERM 6 YEAR PATIENT SATISFACTION AND QUALITY OF LIFE OUTCOMES AFTER AN ADVANTAGE SLINGS FOR STRESS URINARY INCONTINENCE	Balachandran, Duckett	Abstract
2008-08-01	Prospective evaluation of the safety and efficacy of the Apogee system for treatment of vault prolapse	Balakrishnan, et al	Journal of Obstetrics and Gynaecology; 28(6): 618–620
	PROSPECTIVE MULTICENTRE OBSERVATIONAL TRIAL OF COMPOSITE POLYGLACTIN/POLYPROPYLENE MESH (VYPRO* MESH) FOR RECONSTRUCTION OF RECURRENT ANTERIOR VAGINAL WALL PROLAPSE	Balmforth, Cardozo	Poster
2011-01-01	Comparison of transobturator tape (TOT) vs Burch method in treatment of stress urinary incontinence	Bandarian, et al	Journal of Obstetrics and Gynaecology, August 2011;31:518-520
2006-01-01	Abscess formation following trans-obturator tape procedures	Banks, et al	Int Urogynecol J (2006) 17 (Suppl.. 2):
2005-12-01	Contemporary views on female pelvic anatomy	Barber M	Cleveland Clinic Journal of Medicine VOLUME 72 SUPPLEMENT 4

2013-01-01	Surgical Techniques for Removing Problematic Mesh	Barber M	CLINICAL OBSTETRICS AND GYNECOLOGY Volume 56, Number 2, 289–302
2006-01-01	Perioperative complications and adverse events of the MONARC transobturator tape, compared with the tension-free vaginal tape	Barber, et al	American Journal of Obstetrics and Gynecology (2006) 195, 1820–5
2012-01-01	Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial	Barber, et al	Obstet Gynecol 2012;119:328–37)
2008-00-00	Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings	Barber, et al	Am J Obstet Gynecol 199, 666 e1-7
2008-03-00	Transobturator Tape Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial	Barber, et al	Obstet Cynecol 2008;111:611--21
2000-01-01	Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse	Barber, et al	Am J Obstet Gynecol 2000;183:1402-11
2009-01-01	Defining Success After Surgery for Pelvic Organ Prolapse	Barber, et al	Obstet Gynecol 2009;114:600–9
1997-01-01	Intraligamentous Nerves as a Potential Source of Pain After Sacrospinous Ligament Fixation of the Vaginal Apex	Barksdale, et al	Int Urogynecol J 8:121-125
2015-02-28	The impact of boundary conditions of surface curvature of polypropylene mesh in response to uniaxial loading	Barone, et al	Journal of Biomechanics
2008-01-01	A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study	Barry, et al	Int Urogynecol J (2008) 19:171—178
2014-01-01	Management of Mesh Complications after SUI and POP Repair: Review and Analysis of the Current Literature	Barski and Deng	BioMed Research International
2012-07-21	Transvaginal Profit mesh surgery due to advanced pelvic organ prolapse does not impair female sexual function:a prospective study	Bartuzi, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 165 (2012) 295–298

2013-01-01	Three-year results from a randomised trial of a retropubic mid-urethral sling versus the Miniarc single incision sling for stress urinary incontinence	Basu, Duckett	Int Urogynecol J
2010-01-01	A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence	Basu, Duckett,	BJOG 2010;117:730—735
2001-00-00	Pain and Functional Impairment 1 Year After Inguinal Herniorrhaphy: A Nationwide Questionnaire Study	Bay-Nielsen, et al	ANNALS OF SURGERY Vol. 233, No. 1, 1-7
	Principles of Biomedical Ethics	Beauchamp, Childress	
2011-08-31	Literature Review of pelvic Organ Prolapse (POP) Repair Transvaginal Mesh	Becker & Associates Consulting, Inc	
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Documents without bates numbers relied upon by Dr. Blaivas for Wave 1 sling reports

Date	Description
2015-01-01	Gynecare TVT Obturator System Instructions for Use
2015-01-01	Gynecare TVT EXACT Instructions for Use
2015-01-01	Gynecare TVT ABBREVO Instructions for Use
2015-01-00	Gynecare TVT Instructions for Use
	Operation Abbrevo Video
2006-11-20	C4001 POLYPROPYLENE MSDS
2005-04-13	C4001 POLYPROPYLENE HOMOPOLYMER MSDS
2004-03-12	C4001 POLYPROPYLENE HOMOPOLYMER MSDS

Testimony relied upon by Dr. Jerry Blaivas for Wave 1 sling reports

Document Date	Testimony
4/5/2012	Deposition of Piet Hinoul
4/6/2012	Deposition of Piet Hinoul
9/12/2012	Deposition of Charlotte Owens
9/13/2012	Deposition of Charlotte Owens
5/22/2013	Deposition of Daniel Burkley
5/23/2013	Deposition of Daniel Burkley
5/30/2013	Deposition of Martin Weisberg
5/31/2013	Continued Videotaped Deposition 30(b)(6)of Martin Weisberg Volume II
6/20/2013	Videotaped Deposition of Christophe Vailhe
6/21/2013	Continued Videotaped Deposition of Christophe Vailhe Volume II
6/26/2013	Deposition of Piet Hinoul
6/27/2013	Deposition of Piet Hinoul
7/24/2013	Videotaped Deposition of David Brown Robinson Volume I
7/25/2013	Videotaped Deposition of David Brown Robinson Volume II
7/29/2013	Videotaped Deposition of Joerg Holste
7/30/2013	Continued Videotaped Deposition of Joerg Holste
8/9/2013	Continued Videotaped Deposition of Martin Weisberg Volume III
9/11/2013	Videotaped Deposition of Brigitte Hellhammer
9/11/2013	Videotaped Deposition of David Brown Robinson Volume III
9/11/2013	Deposition of Daniel Lamont
11/6/2013	Deposition of Richard Isenberg
1/7/2014	Videotaped Deposition of Thomas A. Barbolt
1/8/2014	Deposition of Thomas Barbolt Volume II
1/13/2014	Deposition of Piet Hinoul
2/3/2014	Deposition of Daniel Smith
2/4/2014	Deposition of Daniel Smith
2/11/2015	Trial testimony of Katrin Elbert